A Dissertation submitted to

The Tamil Nadu Dr. MGR Medical

University in partial fulfilment of the

degree MS (Branch I) General Surgery,

April 2015.

Randomised controlled trial to assess the effect of normal saline wound irrigation in reducing surgical site infection after elective open colorectal resections

CERTIFICATE

This is to certify that the dissertation titled "**Prospective randomised controlled trial to assess the effect of normal saline wound irrigation in reducing surgical site infection after elective open colorectal resections**" is a bonafide work of **Dr. Augustin Abraham T**. in partial fulfilment of the requirements for the **MS General surgery Branch-I** examination of **The Tamilnadu Dr.M.G.R. Medical University** to be conducted in April 2015.

Guide:	**Head of the Department:**	**Principal:**
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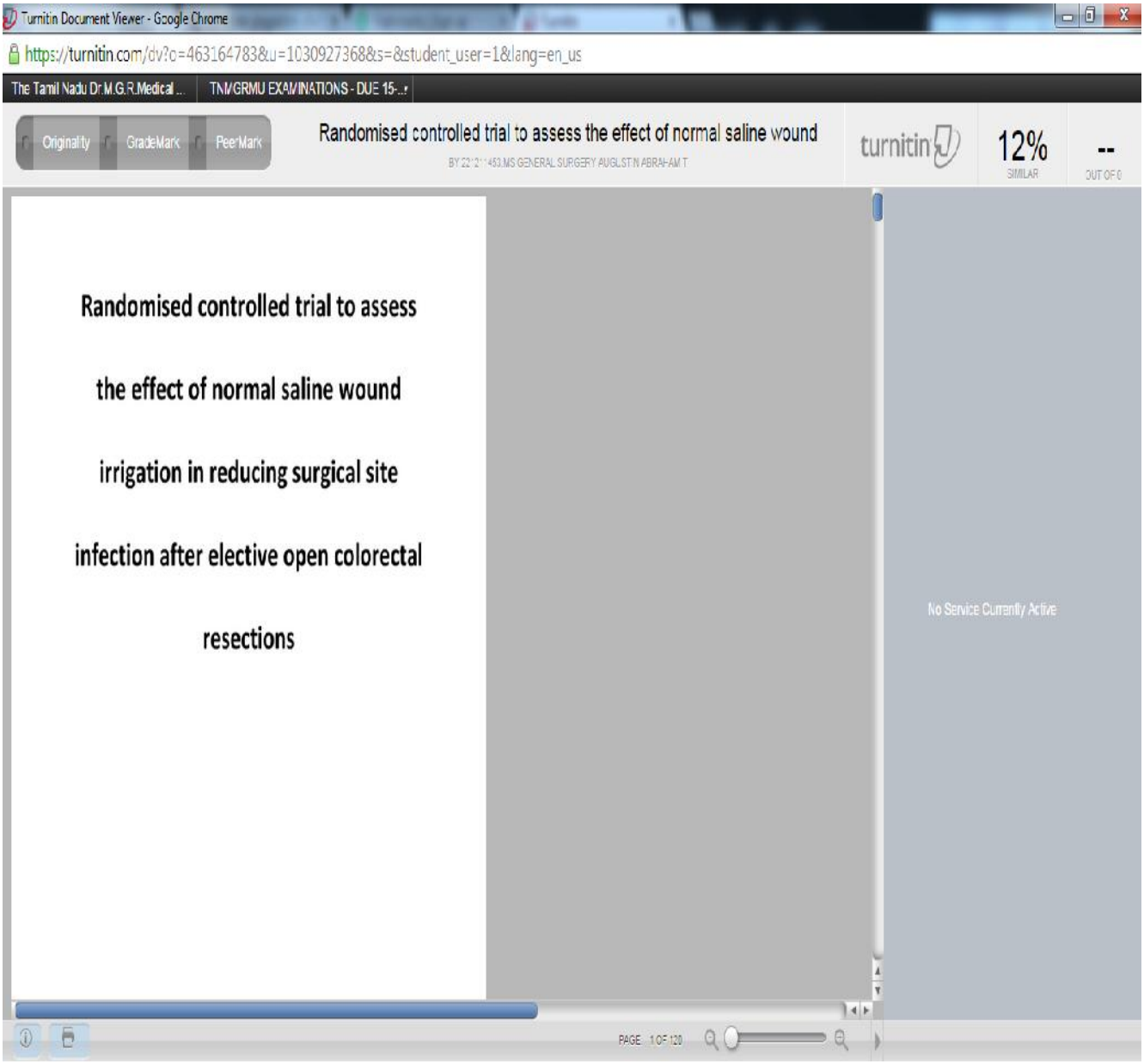
DECLARATION

I hereby declare that this dissertation titled "**Prospective Randomised controlled trial to assess the effect of normal saline wound irrigation in reducing surgical site infection after elective open colorectal resections**" was prepared by me in partial fulfilment of the regulations for the award of the degree of MS General Surgery of the Tamil Nadu Dr.MGR Medical University, Chennai. This has not formed the basis for the award of any degree to me before and I have not submitted this to any other university previously.

Vellore Dr. Augustin Abraham. T

PLAGIARISM CHECK



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November 2, 2012

Dr. Augustin Abraham T
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Sub: **Fluid Research grant project NEW PROPOSAL:**
Does normal saline wound irrigation prevent surgical site infection after colorectal resections?

Dr. Augustin Abraham T, PG Registrar, General Surgery, Dr. Mark Ranjan Jesudason, Dr. Benjamin Perakath, Dr. Rohin Mittal, General Surgery

Ref: IRB Min. No: 7958 dated 22.08.2012

Dear Dr. Augustin Abraham

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "*Does normal saline wound irrigation prevent surgical site infection after colorectal resections?*" on 22nd August 2012.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Information Sheet and Consent Form (English, Tamil, Hindi and Telugu)
3. Cvs of Drs. Rohin Mittal, Mark Ranjan Jesudason, Benjamin Perakath
4. A CD containing documents 1 – 3

The following Institutional Review Board (Research & Ethics) members were present at the meeting held on August 22, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMC	Clinician
Dr. Suresh Devasahayam	BE, MS, PhD	Professor, Bioengineering, pCMC	
Dr. George Thomas	MBBS, D Ortho	Chairperson (IRB) & Orthopaedic Surgeon, St. Isabel Hospital, Chennai & Former Editor, Indian Journal of Medical Ethics	External
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We approve the project to be conducted as presented.

The Institutional Review Board expects to be informed about the progress annually of the project, any serious adverse events occuring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of Rs 49,000/- (Rupees Forty nine thousand only) will be sanctioned for 18 months.

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr Nihal Thomas
MBBS MD MNAMS DNB (Endo) FRACP(Endo) FRCP(Edin)
Secretary (Ethics Committee)
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CC: Dr. Mark Ranjan Jesudason, Professor, Department of General Surgery Unit 2, CMC

3

Clinical Trial Details (PDF Generation Date :- Thu, 09 Oct 2014 22:47:35 GMT)

CTRI Number	CTRI/2012/12/003197 [Registered on: 10/12/2012] - **Trial Registered Prospectively**
Last Modified On	22/08/2014
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Preventive
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A research to study the effects of normal saline wound irrigation on surgical wounds.
Scientific Title of Study	Does normal saline wound irrigation prevent surgical site infection in colorectal resections.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

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ACKNOWLEDGEMENTS

I thank God Almighty for all His help, mercies and counsel.

I thank my guide, Dr. Mark Ranjan Jesudason, the head of the Department, Dr. Benjamin Perakath and my co-guide, Dr.Rohin Mittal for all their support, direction and encouragement.

I thank all my teachers, for their support for completing this thesis.

I specially thank all the patients for their participation despite the burden of their illness.

Contents

ABSTRACT

TITLE: Prospective randomised controlled trial to assess the effect of normal saline wound irrigation in reducing surgical site infection after elective open colorectal resections

DEPARTMENT: GENERAL SURGERY

DEGREE & SUBJECT: MS GENERAL SURGERY

NAME OF THE CANDIDATE: DR. AUGUSTIN ABRAHAM. T

NAME OF THE GUIDE: DR. MARK RANJAN JESUDASON

OBJECTIVES

1.To compare the rate of abdominal incisional surgical site infection in the study arm –normal saline wound irrigation with that in the control arm, no wound irrigation, in all the open elective colorectal resections in General surgery unit 2.

2. To identify other risk factors for surgical site infection.

METHODS

This is a randomised double blinded controlled trial. Patients undergoing elective colorectal resection were recruited as per the inclusion and exclusion criteria after informed consent and randomly allocated to either the study arm (receiving normal saline wound wash) or the control arm (receiving no wound wash). The surgical wound was inspected periodically until 30 days after the operation. Data was entered in epidata spreadsheet. Chi-square test, the test

of significance was used to compare the two groups. Also Chi-square values of the other risk factors were calculated and analysed using SSPS software version 17. Risk factors with p value less than 0.05 were considered significant.

RESULTS:

There was no statistically significant difference in the incidence of incisional surgical site infection between the two arms. None of the other factors that were studied had any association with incisional surgical site infection.

Conclusion:

There is no significant benefit from washing the surgical wound with normal saline before skin closure in preventing SSI in the patients undergoing elective colorectal operations.

Randomised controlled trial to assess the effect of normal saline wound irrigation in reducing surgical site infection after elective open colorectal resections

INTRODUCTION

Surgical site infection:

Surgical site infection (SSI) is a common cause of morbidity and prolonged hospital stay among patients undergoing surgical operations.It decreases the health associated quality of life and increases the risk of mortality.(1)(2)(3)It is a leading risk factor for readmission during the first 30 days after hospital discharge.It increases the hospital expenses significantly.(2)(4) In addition to causing harm to the patient, SSI increases the health care expenses by increasing the length of hospital stay, doctor visits, dressings and home care. So SSI results in an increased burden not only on the patient but also on the health care giver. This also increases the overall cost of hospitalisation.

SSI constitutes an important goal of improvement in surgical care. It is being used as a good indicator of quality of surgical care provided in an institution.(5) Infections following an operation are definitely preventable to a certain extent. There are multiple pre operative, intra operative and post operative factors which can influence the development of incisional surgical site infection.

The following is a summary of preventive measures recommended according to NICE guidelines(6)for prevention and management of surgical site infections.

Preoperative phase:

- Preoperative showering is advised using soap. This can be done prior to the operation or the day of the planned procedure.
- The removal of hair in the surgical site is routinely avoided. This is done to avoid infection at the operated site. The use of razors is not recommended as this can increase incidence of infection. Electric clippers can be used safely if hair reoval is necessary on the day of the surgery.
- Appropriate theatre clothes is also mandatory for all health care professionals..
- Any health care giver who is inside the operation theatre should wear the required sterile/unsterile theatre attire. The movement of staff within theatre premises should be minimal and confined only to the essential staff.
- Mechanical bowel preparation and nasal decontamination are avoided
- Appropriate antibiotic prophylaxis as per local antibiotic resistance pattern is required in the following settings:
    - Clean operation where an artificial prosthesis or an implant is used, for example – hernia surgery.
    - Clean-contaminated operation and
    - Contaminated operation
- Clean operations where prosthesis is not used and are of short duration the routine use of antibiotics is not advised. Before giving antibiotic prophylaxis, the timing(within 60 minutes of the skin incision) and pharmacokinetics (for example, the serum half-life) and necessary infusion time of the antibiotic should be considered. A dose of

antibiotic prophylaxis should be repeated when the operation duration is prolonged. In setting of dirty wounds and infected wounds therapeutic antibiotics is recommended.

Intraoperative phase:

- Hand decontamination before the operation. This can be done using an alcohol based hand rub or an antiseptic solution.
- Incise drapes which are non-iodophor should not be used since they might increase the chance of infection.
- Antiseptic skin preparation, preferably alcohol based Chlorhexidine in non-mucosal areas. However, it is still controversial as to which of the antiseptic solution is better than the other.
- Surgical incisions are preferably made with skin knives as diathermy use can predispose to surgical site infection.
- Inadvertentperioperative hypothermia should be avoided
- Optimaloxygenation and adequate perfusion during surgery have to be maintained.
- Wound irrigation and intracavity lavage are avoided.

Post operative phase:

If we consider that a patient has wound infection in the surgical site post operatively, antibiotic that covers the likely causative organism is used. Debridement is done if required.

In colorectal resections, there is high morbidity and mortality related to surgical site infections. It is the practice of the surgeons to irrigate with normal saline in wound of patients

who are likely to develop surgical site infections. There are two studies(7)(8) done comparing the rate of surgical site infection when the surgical wound is irrigated and when not.These were done in patients undergoing gynecological and general surgical operations. There is no study among patients who have electively undergone colorectal surgeries. Therefore, there is a need for a study to show that normal saline wound irrigation decresases the risk of abdominal SSI following colorectal operations.

Hence, through this research trial, it was planned compare the incidence of abdominal surgical site infection after colorectal resections in the post operative period between the group receiving wound irrigation with normal saline and the group receiving no wound irrigation.

AIM:

To assess the effect of normal saline wound irrigation in reducing the surgical site infection after elective colorectal resections.

OBJECTIVES:

1. To compare the rate of abdominal incisional surgical site infection in the study arm – normal saline wound irrigation with that in the control arm, no wound irrigation, in all the open elective colorectal resections in General surgery unit 2.

2. To identify other risk factors for surgical site infection

LITERATURE REVIEW

REVIEW OF LITERATURE

Definition of surgical site infection

Epidemiology

Classification of wounds

Stratification of risk for SSI

Determinants of surgical site infection

- Bacteria
- Surgical site
- Host defence mechanisms

SSI in colorectal operations

Why normal saline wound irrigation in colorectal operations

The use of various irrigating solutions

Various methods and antiseptic solutions for wound irrigation

Normal saline wound irrigation in other operations

Normal saline wound irrigation in colorectal operations in guinea pigs

Definition of surgical site infection:

The standard definition of surgical site infections (SSIs) that we have used is provided by the Centre for Disease Control. This was published in the year 1992 and was updated subsequently in 2003. According to the guideline layed out, SSIs are divided into two entities – incisional infection and infections involving organ space or deep infections(9)(10)

Incisional SSIs are divided into 2 categories: superficial infection, which includes skin and the underlying subcutaneous tissue. Involvement of the muscle and fascia is categorised as deep infections. Dividing surgical infections into the above mentioned categories is vital as the aetiology and management of both these entities are different and the prognosis is also different. (11).

Both the categories involve infection occurring within a month of the procedure and upto a year if an artificial prosthesis was used during the operation.

Superficial incisional surgical site infection diagnostic criteria:

Infection that is confined to the skin and underlying tissue (sub-cutaneous) and having at least one of the following –

- Pus discharge which may or may not be confirmed using the laboratory.
- Clinical parameters:
    - Increased pain
    - Tenderness
    - Swelling of tissues

- Erythema
- Increased warmth
- Superficial incision deliberately opened by surgeon

- Diagnosis is made by the attending physician.

Deep incisional surgical site infection:

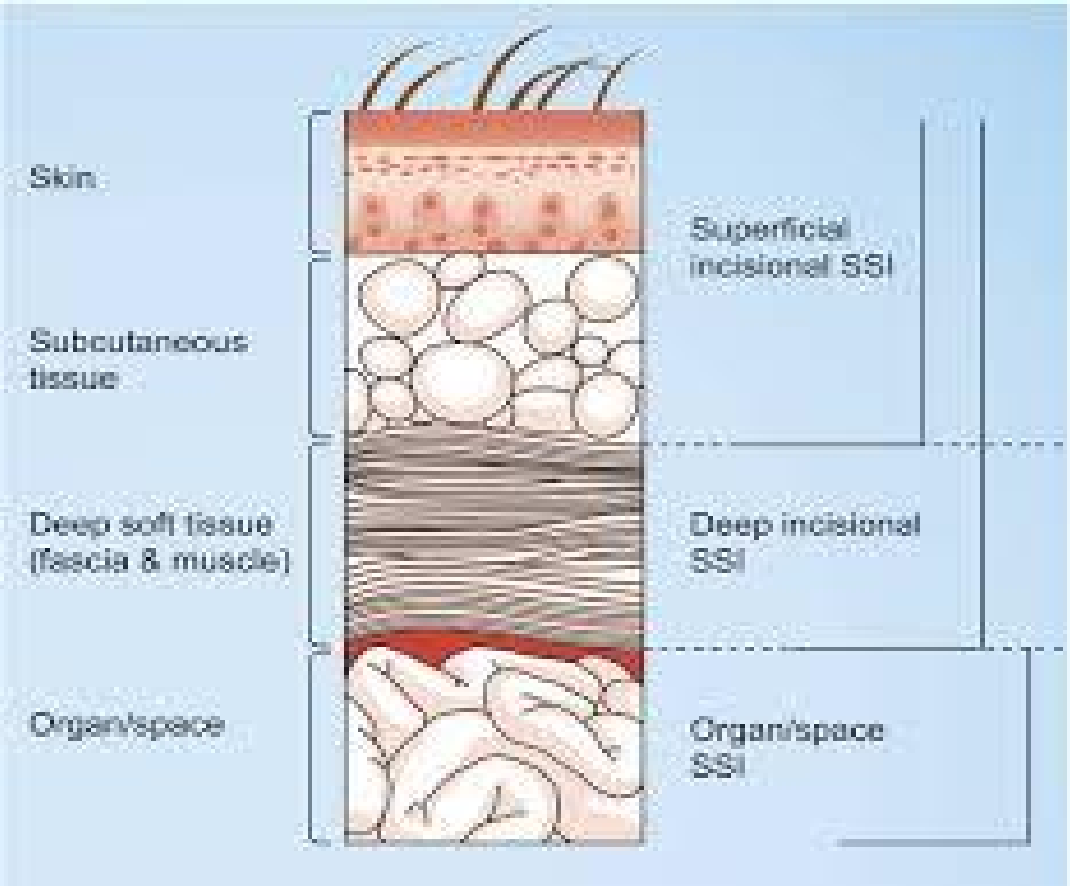
- This is diagnosed when there is infection of the deeper structures, this includes fascia and muscles and one of the following:
  - Pus discharge from the muscles or fascia without organ space infection.

    .
  - Spontaneous breakdown of the deeper incisional space or if deliberately opened by a physician when infection is suspected.
  - Pus discharge suggestive of an abscess is found on
    - Clinical examination, during an operative procedure, proven in the histopathology lab or if there is radiological evidence of the same.
  - Diagnosis made by the physician during ward rounds..

Organ space surgical site infection:

- This entity is reserved to diagnose an infection of a space/organ that is infected as a result of the procedure. This does not include the previously mentioned entities. The following inclusion details have to be met-
- Murky fluid or pus discharge in the drain which has been placed in the organ space.
- Presence of an organism which is confirmed by microbiological examination.

- An abscess involving the organ or space which is diagnosed either clinically, during a procedure such as re-operation or with the assistance of radiological imaging..



Epidemiology of surgical site infection:

The incidence of surgical site infection in patients undergoing a major operation in United States is about 2-5% each year.(12)(13)The risk of having an infection at the operated site is different for operations at different anatomical locations .

Operations of face, neck and head for cosmesis pose a much lower risk of SSI than operation in the lower GI tract for example colon resection. Malignancy, increased age and comorbid illnesse further complicate the scenario.

An elective operation has lower SSI rate than do an emergency operation.

Rate of surgical site infections (SSIs) for various procedures also differ based on the population, size of the hospital, experience of the operating surgeon and methods used for monitoring and surveillance. Non-teaching hospitals usually have the low rates of SSI compared to teaching hospitals (4.6 versus 8.2 percent, respectively).(14) Oncological operations have increased incidence of having infections. This is reported in a few studies. (15)

Stratification of different operations into classes (that have similar risks for infection) is vital, so that

1. Preventive methods can be appropriately planned among similar individuals and
2. When infection rates differ from accepted international trends, quality monitors can be implemented.

Classification of surgical wounds:

A surgical wound can be classified as clean, clean contaminated, contaminated or dirty based on amount of bacterial load in the surgical site during operation.(16)

Class I/Clean:	No inflammation. Alimentary tract is not entered Respiratory tract is not entered Genital or urinary tractis not entered. Clean wounds are closed primarily.
Class II/Clean-Contaminated:	If there is no inflammation or infection. If the bowel(alimentary tract), respiratory tract or the urogenital system is entered in a planned and prepared manner then they are classified as clean contaminated wounds.
Class III/Contaminated:	Fresh, open wounds Break in the asepsis protocol GIT contents spillage Entry into the body cavities when there is infection Incisions where acute inflammation(non-purulent) is encountered are included in this class .
Class IV/Dirty-Infected	Devitalised tissue Faecal contamination Dirty wounds and open traumatic wounds.

Stratification of risk for SSI:

Recognized factors associated with SSI are necessary to stratify patient's risk and to design prevention strategies. Surgical wounds were stratified in 1964 based on the landmark publication in 1964 by The National Academy of Sciences–National Research Council. (17)Wounds were classified based on endogenous bacterial contamination. There was non-controversial evidence to suggest that wound stratification is necessary. This allowed for comparability of wounds between hospitals, services and time periods.

The operation site, operative time and the clinical status of the patient were identified as the risk factors for wound infection as defined in 1980s by SENIC. (18)

The surgical duration, wound classification and ASA classification greater than 2 were risk factors for wound infection as defined by National Nosocomial Infection Surveillance (NNIS).(19) These risk factors or categorization can also be used outside the United States of America. (20)

The use of laparoscopy for GI operations specially colorectal operations was added to the above mentioned three risk factors. This model was published in 2010 and was incorporated with the CDC risk factors for wound infection(21)

The major drawback with the SENIC and NNIS assessments was that they did not include factors such as smoking, glycemic control, body temperature and tissue oxygenation. All these factors are difficult to monitor and although they definitely affect clinical outcomes, they are statistically difficult to measure.

P.Gervaz et al published a simple clinical scoring system based on four variables. This system is based on four preoperative clinical parameters – contamination, obesity, laparotomy and ASA grade (COLA) and was constructed so as to help to identify patients at high risk of developing SSI after colorectal resection.(23)

Prevention of SSIs :

Surgical site infections are presumably preventable. There are multiple risk factors and prevention strategies in controlling surgical site infections. Each of these factors has to be taken into consideration and appropriate methods need applied to prevent surgical site infection so that the preventable morbidity of any operation can be reduced.

Historical Perspective(24)

Historically, example of surgical wound care is seen in the battlefield. Gunshot wounds were managed with a cocktail of rose oil, moss from mummy' skull and worms. Ambroise's use of

mixture of cold turpentine, yolk from eggs and rose oil was heralded as a milestone. Inspite of the efficacy of hand hygiene in reducing puerperal sepsis being proved by Semmelweis in the mid-1800s and later popularized by Holmes, hand-washing by surgeons was not established as common practice till early 20th century.

Major operations were almost always followed by infective complications, manifesting as cellulitis lastly progressive soft tissue infections and tetanus with a high mortality rate. In 1867 Joseph lister introduced carbolic sprays to disinfect the surgeon, the operation theatre and the patient. This caused a dramatic reduction in infection rates to less than 10 percent. The concept of asepsis was initially not universally accepted but Lister's results created a case to accept Pasteur's theory that purulence was caused by microorganisms by process of putrefaction. After adopting hand-washing and the use of autoclaved sterile gowns, gloves and supplies, infection rates for clean operations approached close to modern rates. But, GI operations still carried high incidence of infection as the organism was endogenous in origin.

Early clinical studies done in the 1950s revealed that there was no benefit or an increase in the wound infection rates after the introduction of routine antibiotics. There was also the fear of resistant strains developing.(25)(26)(27)

This apparent failure of antibiotic prophylaxis was fallacious and Burke et al in 1960 showed a flaw in the previous studies. He administered a single dose of antibiotic at various times and concluded that the delay in antibiotic administration was the reason for failure of prophylaxis. If antibiotics were administered before 3 hours of the procedure they were as good as not administering antibiotics at all. He therefore highlighted the importance of timing of antibiotic prophylaxis.

An infection in the surgical site arises as a result of inoculation with a higher bacterial load than the body can contain.(29) Therefore, dirty wounds and immunosuppression increased incidence of SSI.

This is true specially in colorectal surgery as there is a higher bacterial load that has to be overcome.

The risk factors studied in the development of SSI are the following:

Pre-operative

Intra-operative

Post-operative

The following pre-operative risk factors have been identified –

Age,

Gender,

Diabetes mellitus, Airway disease such as COPD,

Heart ailments,

Chronic liver disease,

Steroid or immunosuppressive drugs,

Body mass index (BMI),

Nutrition status of the patient

Anemia

Colorectal pathological diagnosis which involves the stage of the disease and presence or absence of neoadjuvant radiation and chemo therapy.(30)

Intraoperative and postoperative factors that can influence arethe following:

Emergency operation,

Colorectal resection type (eg. Right hemicolectomy vs low anterior resection),

Multivisceral resection,

Ostomy creation (ileostomy or colostomy),

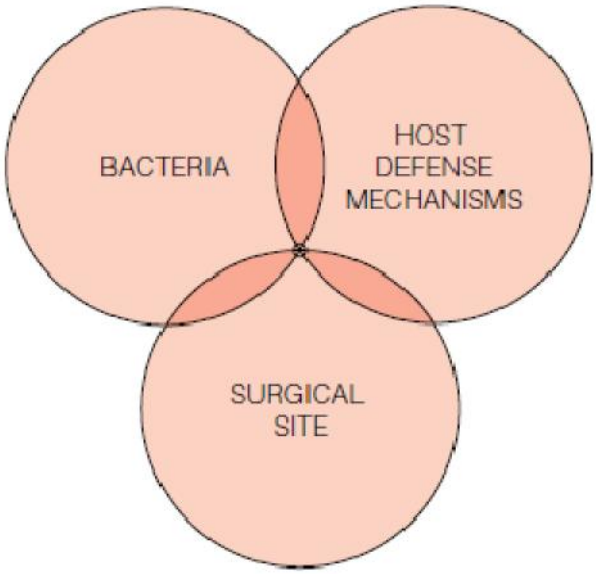
Duration of the procedure

Postoperative ICU care,

Blood transfusion (30)

Determinants of infection:

Risk assessments integrate thethree determinants of infection: bacteria, local environment (i.e) the surgical site and systemic host (patient)defenses(22)



In a homeostatic state,the surgical site, bacteriaand hostdefence mechanisms (represented by three circles) intersect at apoint indicating zero probability of sepsis(22)

BACTERIA

The influence of bacteria on surgical site infection can be studied in four major components: the bacterial inoculum, the pathogenicity of organisms, source of bacteria and bacterial properties.

BACTERIAL INOCULUM

Most of what is known about bacteria is put to use, in major efforts directed at reducing their numbers by means of asepsis and antisepsis. Without an infecting agent, no infection will result. The infectivity of an organism is based on the size of the bacterial inoculum. Wounds are classified according to whether the inoculum of bacteria in the wound is likely to be large enough to overcome local and systemic defence mechanisms of the host and thus result in infection. According to one study, the number of bacteria present in the wound at the end of an operation was the most important factor in the development of a surgical site infection.(31) Another study quantitated this and explained how local environmental factors might be integrated in knowing and understanding .(32) In the era before prophylactic antibiotics were used, as well as during the early phases of antibiotic use, there was a close relation between the classification of the surgical wound (which is based on the probability of a significant inoculum) and the rate of surgical site infection.(17)(33) This relation is still important and other risk factors have been also found to play a major role.(18)(34)

SOURCES OF BACTERIA

Endogenous bacteria which are present in colonies have been found to be major cause of SSI than exogenous bacteria. In clean - contaminated, contaminated and dirty/already infected surgical wounds, the source and the number of bacteria present are functions of the patient's clinical condition and the specific organs which are being operated. Infected operations are

those in which pus and infected tissue are drained or removed, and bacterial inoculum is already present in the surgical site. The inoculums of the organism may be as high as 10^{10} bacteria/ml, some of which may already be causing an infection. Also, some organism will be in the growth phase rather than the lag or the dormant phase and so could be more pathogenic. When the wound is heavily contaminated, it is best managed by delayed primary closure. This ensures that the wound which is almost certain to develop a wound infection is not allowed to close over a bacterial inoculum.

When remote infection is present, patients should not undergo an elective operation since it is associated with an increased incidence of wound infection.(17) In patients having UTI, surgical wounds frequently become infected with the same micro-organism. Remote infections must be treated appropriately and the operation should be planned on a later date. If the operation can't be delayed to another appropriate day, prophylactic or therapeutic antibiotics are recommended.

Control of sources of bacteria:

Preoperative methods of reducing patient flora (especially reducing endogenous bacteria) are of major concern e.g. Mechanical bowel preparation, antimicrobial baths and preoperative hair removal causing trauma to the shaved areas and the small areas of inflammation and infection becomes inevitable.

If hair removal is needed, clipping rather than shaving, is preferably done in the operation room just before the operative procedure (35)(36).

In the recent past, the role of the classic bowel preparation has been controversial. (37)(38)(39)(40)(41)

When infection develops after clean operations, particularly those in which implants are placed, the skin is the most important source of the infecting bacteria though endogenous organisms may also be involved occasionally. Operating room (OR) personnel are the most

important source of exogenous bacteria.(42)(43)(44) Both the operating team—surgeon, assistants, nurses, and anaesthetists—and OR air were reported as important sources of bacteria.

In a study done by the National Academy of Sciences–National Research Council, in 1964 ultraviolet light was efficacious only in the limited situations of clean and ultraclean cases.5. There were minimal numbers of endogenous bacteria, and ultraviolet light controlled one of the exogenous sources. It is possible to get good results in clean cases with implants without using UVL systems. However, clean air systems are here to stay. Nevertheless, the presence of a clean air system does not mean that basic principles of asepsis and antisepsis should be abandoned, because endogenous bacteria must still be controlled.

The use of drapes and gowns which are impermeable may therefore be of clinical importance since bacteria can't penetrate impermeable gown and drapes and hence they cannot gain entry to the wound. (45)(46)

Chance of contamination

The chance of contamination is largely depending upon various other factors other than the operation itself. The most prominent one is the expected duration of the operative procedure, which has been significantly associated with the surgical site infection rate.(18)(31)(33) The longer the operation is, the more bacterial accumulation in the surgical wound from the operating team, operating room, instruments and the patient himself. Another risk factor which is not seen in the NNIS risk assessment is an abdominal operation.(18)(19) which involves bacterial contamination. This is because maximum concentrations of endogenous bacteria are located in the abdomen.

BACTERIAL PROPERTIES

Apart from bacterial inoculums, virulence and pathogenicity of the bacteria are also important. The gram-positive cocci are the most pathogenic bacteria in surgical patients are gram-positive cocci e.g., Staphylococcus aureus and Streptococci.

The preoperative hospital stay has been found frequently to be an important factor to surgical site infection rates.(33) Therefore, multiple factors combine to change the preoperative patient who is hospitalized into a susceptible individual. Same-day admission should eliminate any bacterial impact associated with the preoperative hospital stay. Multi resistant bacteria (e.g. MRSA, S. epidermidis, and VRE) can be related with significant SSI. SSIs caused by resistant organisms or unusual pathogens need specific prophylaxis along with surgical care..

PATHOGENIC ORGANISMS

With the exception of clean operations, surgical site infections are recognized as having a polymicrobial cause, involving both aerobic and anaerobic organisms (47)(48)(49)(50)(51)(52) Intra abdominal(organ or space) infections normally reflect the micro-flora of the resected organ.(47)(48) Despite the frequency and prevalence of endogenous anaerobes in surgical wound infections, the Centres for Disease Control and Prevention guideline for the prevention of surgical site infection has recognized S. aureus, coagulase-negative Staphylococci, Enterococcus species, Escherichia coli, Pseudomonas aeruginosa and Enterobacter species as the most frequently isolated pathogens. (53) Unfortunately, this view has been based on only two published reports that provided no indication of the inclusion of anaerobic bacteriology in the associated studies, and hence the

data may have been biased in favour of aerobic and facultative microorganisms.(21) In contrast, Rotstein et al. (54)stressed the polymicrobial nature of almost all surgical infections and commented that the critical importance of aerobic-anaerobic mixtures in these infections had been given relatively little attention.

SURGICAL SITE – (FACTORS RELATED TO THE WOUND AND SURGICAL TECHNIQUE):

Factors related to the surgical site influence development of wound infection since they usually affect the size of inoculum of bacteria which is needed for the development of an infection. In case of a susceptible wound, even a smaller bacterial inoculum will result in development of infection.

INFLUENCE OF SURGEONS ON LOCAL FACTORS

Surgeons affect almost all the local factors that contribute to the development of surgical site infection.(22)Halsted is established the necessity for excellence in techniques in operation room so as to prevent wound infection. His principles stressed on sharp dissection, haemostasis, fine sutures and tissue handling. Ligature en masse, braided or big non-absorbable suture material, dead tissue and seroma or hematoma creation should be avoided. The size of the bacterial inoculum is also influenced by the presence of foreign body which can increase the number of bacteria in a tissue logarithmically. The foreign material could be dead tissue resulting from inappropriate use of cautery device or a suture, a pacemaker or a graft.(22)

The wound hematocrit and antibiotic are the two factors which causes variations in the inoculum of bacteria necessary for development of surgical site infection. Whn there is haemorrhagic fluid is present is more than 8% and antibiotic is not (31) the rate of surgical site infection was 20%. However, in the presence of a wound which is technically sound,even without antibiotic, 1000 bacteria is needed to produce the same infection rate.(32) If antibiotic is present, 10^5 to 10^6 bacteria are needed for the development of surgical site infections.

Drains

The usage of abdominal drains differs between surgeons. While a simple drain may function as exit for drainage of abdominal fluid collection, it can also be an access for the bacteria to enter the abdomen. However, a closed suction drain can decrease the rate of surgical site infection.(55)

A meta-analysis from 2004 narrated the conclusions as follows:

1) After colorectal and hepatic resections with a primary gastrointestinal anastomosis and following an appendicectomy for appendicitis at any stage,placement of drains must be avoided and

2)In case of upper GI surgeries involving oesophagus/gastric resections, drains must be used. Further RCTs are necessary to find out the importance of prophylactic drain placement for operationss, mainly operations of the upper gastrointestinal tract.

Duration of Operation

It has been proven that,(18)(31)(33) wound contamination increases certainly with time. Wounds can get dried up and they are altered and are made susceptible to surgical site infection.

Electrocautery

There will be rise in the incidence of superficial wound infections with usage of electrical cautery. However, when used properly to provide focussed coagulation or to cut tissues which are under traction, there is no charring, less destruction of tissue and there will be less incidence of SSI rate.(56)

HOST DEFENCE MECHANISM (PATIENT FACTORS)

Local Blood Flow

Inadequate local perfusion leads to reduced levels of oxygen in the tissue and so require only les quantity of bacteria to produce infection. These situations arise in a patient in shock and a patient with peripheral arterial occlusive disease. This condition can be overcome by providing supplemental oxygen during and after the operation. This will increase the subcutaneous oxygen level (measured by TcPO2).(57)

Barrier Function

The most clinically feasible way of protecting bowel is early initiation of enteral feeding and administering amino acid glutamine as nutritional support for enterocytes and colonocytes. This can help damaged intestinal mucosa recover.

Advanced Age

During aging, changes that occur functionally and structurally leave the subcutaneous and dermal tissues more vulnerable to SSI. Usually, these body changes are irreversible. Wound infection rates rise with increasing aging up to 65 years of age, after which point the rate seems to decline.(57)

Patient defence Mechanisms

The host's body response to infection is usually to destroy it but it is inhibited by underlying debilitating disease of the patient and other factors in the environment.

Host defence mechanisms are also affected by surgeon related factors and patient related factors.

Surgeon-related factors to improve a patient's systemic responses to surgery are limited. Operation must be carried out with minimal blood loss, maintenance of good amount of intravascular volume, adequate oxygenation of the tissue with good perfusion and avoidance of shock which will reduce trauma and thus decrease the secondary, unintended immunologic effects caused by major operations.

Diabetes is another recognized risk factor of SSI. Good glycemic control during the operation and post operatively, can reduce the incidence of wound infection significantly in a patient who does not have diabetes mellitus and those who have diabetes mellitus. Other important factors are to maintain good oxygenation of tissue and to maintain normal temperature.

Patient factors are different clinical conditions which are related to altered immune response in patients. Advanced age, ASA scoring, intra operative blood transfusion and the use of immunosuppressants like chemotherapy agents are related with a rise in the rate of wound infection. Most of these risks can't be changed; still, patient selection for an appropriate surgery, antibiotic prophylaxis and fine surgical methods can reduce the bacterial inoculums and thus the incidence of SSI. Smoking causes rise in the rate of wound infection. Even a short period of smoking cassation is of help to the patientDrug therapy like NSAIDS can influence patient body defence mechanism.

Operations involving inhalational anaesthetics cause sudden rise in concentration of plasma cortisol. High epidural anaesthesia can modify the steroid induced immune modulation which attenuated the pituitary adrenal activation will be greatly attenuated.

Integration of Determinants of Infection

Applying knowledge of these effects practically, the following 3 steps has to be maintained

1. One should keep the microbial contamination of the wound as much less as possible through aseptic techniques and cleanliness, preparation of surgeon and patient for the operation, pre operatively along with prophylactic antibiotics.

2. Keeping factors that can influence the surgical site in a manner by which they can get rid the lodgement of microbes and thus give a surrounding not conducive for their multiplication and growth.

3. To maintain host defence mechanisms in a condition that the microbial growth is checked at all the time. The above are the important factors influencing infection & need proper application or avoidance appropriately on a day to day basis. Every year there is decrease, in incidence of surgical site infection, whenever these are strictly applied.(22)

It is clear that the risk of wound infection can't be inspected in relation to microbial control alone. Patient factors also play a major role in maintaining microbial counts at lower levels by aseptic technique and antibiotic prophylaxis.(22)Important patient factors are maintaining oxygenation of tissue, blood volume and tissue perfusion.

Preventing SSIs in colorectal operations

Elective colorectal operations are clean contaminated procedures. The post operative complications of colorectal operations constitute a major burden on the morbidity apart from the morbidity caused by the colorectal disease themselves. Among the operations performed for colorectal diseases, most of them are done for malignancy. About 80% of the colorectal operations are done for malignancy.

The SSI rate is substantially higher in individuals undergoing colorectal operations. The current incidence of wound infection in colorectal surgeries, ranges from 5 to 30%.(58)(59) The gross variation in published incidence of wound infection is mainly due to different definitions which are used for defining wound infection. The high incidence is primarily because of the large amount of bacterial colonization present in the large bowel. It is about 10^{11} –10^{12} microorganisms present in every milliliter of stool in the large intestine(60) When wound infection occurs following a colonic operation, it can be expected that the pathogenic organisms causing the wound infection is mainly those bacteria that contaminated the incision during surgery. In almost all colonic operations, the most likely organisms to be encountered are E. coli and Bacteroides fragilis. Other bacteria like Klebsiella and Enterobacter species also contribute. There is highest bacterial density of the anaerobic species such as B. fragilis found in the left colon, sigmoid colon and rectum but they are not consistently cultured since these organisms are obligate anaerobes. Other organism commonly found in colon are Enterococcus species are found commonly in the colon but they do not cause SSI very frequently in immunocompetent host. Prior hospitalisations of

patients or exposure to antibiotics results in alteration of their normal gut microflora and rare gram negative bacteria can be expected. Serratia species, Pseudomonas species and even Acinetobacter species. can be found in these later circumstances.

Staphylococcus aureus colonisataion occur in about 20% to 25% of patients in U.S and these bacteria can be found in surgical site infection after colonic operation and almost all are community-associated and methicillin-resistant organisms.(61)

‘

Preoperative factors:

Preoperative shower with skin antiseptics even though widely practiced, has no clear evidence that alters the incidence of SSI. (22)

Skin antiseptic during operation:

Several skin antiseptic agents have been used to decrease the skin bacterial contamination, before skin cut is made. Many studies have been conducted to asses the efficacy of various topical antiseptic solutions to stop wound infections in clean contaminated wounds.

A multicentric trial comparing Chlorhexidine and povidone-iodine for decontamination of operation site in clean-contaminated operations, has proved a statistically significantly lesser incidence of wound infection in the chlorhexidine arm than in the povidone-iodine arm.(62) In colonic and rectal operations, patients on whom chlorhexidine was used had a higher wound infection rate compared with the incidence in the patients on whom povidone-iodine was used.

Another single institution trial examined three different skin antiseptics and each solution was used.(22) each antiseptic solution ws used sequentially, each solution for 6 months. The difference in the rate of infection was significant between the povidone-iodine arm & iodine povacrylex in isopropyl alcohol arm, when the difference between 2% chlorhexidine arm and 70% isopropyl alcohol arm was compared.(63)

There are other recent studies which have proven the superiority of the Chlorhexidine solution over Povidone Iodine solution and so chlorhexidine-alcohol must be used wherever possible.

Wound protectors:

Theoretically, wound protector device will decrease the contamination of the surgical site with and decrease mechanical trauma by protecting it from contaminants. Therefore, use of surgical site protectors as a preventive measure of wound infection have been studief by several authors. Raahave and his colleagues have seen a considerable decrease in density of bacteria in the surgical site, when a surgical site edge protector device was applied.(64) However, there was no statistically significant decrease in the incidence of surgical site infection when the device was used and so there is no relation with decreasing SSIs when wound protectors are used.(65)(66)(67)

In about 4 RCTs on patients undergoing colorectal operation, there was no correlation found in the rate of wound infection and the use of wound protector device when a patients undergoes an abdominal operation.(68)(67)

Another retrospective study assessed the utility of wound protection device in laparoscopic operations to externalize the specimen and for anastomosis. There was no statistically significant difference between the group in which wound protector device was used and the group where it was not used.(69)

An RCT done on patients undergoing trans-abdominal operations showed a significant decrease (29 to 14 percent) in the incidence of wound infection when impervious surgical site protector device was used.(70) There was drastic reduction in the infection rate when the wound was found contaminated pre operatively.

A non-randomized study compared the rate of surgical site infection in patients undergoing GI operations when wound protector instrument was used and when it was not used. There was reduction in the surgical site infection from 15 to 2.4%.(66)

There has been few other RCTS which studied different types of protection devices, in various surgical procedures and the results have been unequivocal. This implies that the role

of surgical site protectors in reducing the surgical site infection rate, in various abdominal operations, is not clear ,(22) and more RCTs are necessary to clarify this question.

Mechanical bowel preparation:

Mechanical bowel preparation (MBP) is commonly done to decrease fecal contamination intra operatively before elective colorectal operations. Studies have aimed at comparing the rate of septic complications like surgical site infection, fascial dehiscence and anastomotic leakage with mechanical preparation. In a multicentric randomized trial done in Netherlands, patients who underwent mechanical bowel preparation and who did not were compared with anastomotic leakage as the primary outcome. The incidence of anastomotic leakage did not differ between the two groups. Patients who had MBP developed fewer abscesses after anastomotic leak compared to those who did not. Fascial dehiscence and other septic complications along with mortality rates were same in both the groups.

A review article by Slim et al,(39) included 7 studies (Total number – 1454 patients, mechanical bowel preparation(MBP) was given to 720, and others did not have bowel preparation) and they were followed up for 7-60 days. There was higher rate of anastomotic leakage in patients who had bowel preparation. In addition there was no statistically significant difference in the rate of surgical site infection and rates of other complications between the group who had MBP and who did not have MBP.(39)

In the background of these studies, which have concluded that bowel preparation did not have additional benefits in reduction of post operative complications but can result in more anastomotic leakage, colorectal surgeons from Canadian society have recommended pre operative MBP to be avoided.

Use of laparoscopy:

The report that there has been reduction in the post operative infectious complications of the wound, by the use of laparoscopy, has been confirmed by few meta-analyses.

The incidence of surgical site infection was studied in a meta analysis containing 25 randomized trials and 1771 subjects. The trial compared the rate of surgical cite infection in operation group with laparoscopic group and found a statistically significant reduction in the laparoscopic group. But, the study did not show any difference in the rate of development of intra abdominal collection post operatively(71)

Another meta-analysis which included many larger randomized studies which were partly completed when first analysis was conducted, Colon Carcinoma Laparoscopic or Open Resection or COLOR and Conventional versus laparoscopic assisted surgery in colorectal cancer [CLASICC] studies, was published after 12 months. There was significant reduction in the complications of the surgical site in the laparoscopic operation arm when compared with the patients who underwent open operation.(72)

In five of the largest multicentric trials, where patients undergoing laparoscopic surgery was compared with patients undergoing open surgery, each study report separately demonstrate that there was no statistically significant difference in the rate of surgical site complications and the morbidity between both the study arms.

Limitation of these trials is that patients undergoing laparoscopy converted open operation was considered in laparoscopic procedure arm as intention to treat. There is a chance of data getting skewed since patients with large open incision was included in laparoscopic arm.

Another limitation of these studies is that patients with colon cancer, alone was included. Patients with inflammatory bowel disease and diverticular disease were not included (22)

These large RCTs, though as individual studies, have not demonstrated any difference in surgical site infection, as meta-analysis which includes many smaller trials, they have shown significant reduction in the rate of surgical site infection. Hence, it is possible that the risk of of surgical site infection in patients undergoing laparoscopic operation, is not more than in patients undergoing open operation and can well be less. So, while measures to decrease wound infection are considered, laparoscopic colorectal resection must be tried whenever possible.(72)

Prophylactic placement of intra abdominal drain:

It was believed that prophylactic placement of intra abdominal drain might decrease the incidence of surgical site infection by allowing the drainage of accumulated blood and fluid and allowing early detection of anastomotic leakage.(22) However, it has been argued that prophylactic placement of intra abdominal drain can actually increase the incidence of complications by causing anastomotic site infection because it allows communication with skin flora. Various studies have been performed examining this aspect. Evidence shows prophylactic placement of intra abdominal drain can be detrimental and use of intra abdominal drain should be avoided.

Suturing of fascia:

Different techniques and different suture materials to close the fascia have been studied. A metaanalysis that assessed different fascial closure techniques with different suture materials did not show any significant difference in the incidence of wound infections.(39) Another clinical trial compared fascial closure with slowly absorbable suture material continuously

with facial closure with rapidly absorbable suture in an interrupted manner, did nto show any statistically significant difference in the rate of SSIs .(73)

While closing the fascia continuously an ideal suture length to wound length ratio should be > 4 so as to decrease the rate of incisional hernia.(74) as evidenced in a recent RCT

Also, an RCT comparing rapidly absorbable suture covered with antiobiotis with slowly absorbable suture showed significant decrease in the incidence of SSI.(75)

A study comparing continuous versus interrupted closure of fascial layer, did not show any variation in the incidence of SSI.

NS wound irrigation helps in improving the outcome of surgical wounds

In tissue healing the microbes, dead tissue and foreign body are scavenged because of increased vascular permeability during the phase of inflammation of the tissue in response to tissue injury e.g. complement cascade activation, cytokine release, cytotoxicity, etc.(76) but when there is immunodeficiency bodies defence mechanism to overcome microorganisms fails which can result in poor neovascularisation and granulation of tissue and infection ensues.

Bacterial contamination is of fundamental importance in the development of wound infection. Bacteria associated with SSI reflect the area that provided the inoculum for the infection to develop. S. aureus and related species Staphylococcus remain the commonest bacteria colonized from wounds. However, at locations where high volumes of gastrointestinal (GI) operations are performed, the predominant bacteria will include Enterobacter species and Escherichia coli. In most studies, group D Enterococcus continues to be a common pathogen isolated from surgical site infections.(77) . There is significant decrease in the number of bacteria present during closure of skin when normal saline is used to irrigate the surgical site in animal models.(76)

Hence, it is considered that intra operative normal saline wound irrigation helps in decreasing the bacterial contamination of the wound from the intestines and thus decreasing the rate of wound infections.

Use of various irrigating solutions

Sindelar and Mason3,4 studied the effects of Povidone Iodine solution on wound infection through an randomised controlled trial. Patient aged between 9 and 80 years and undergoing abdominal, GI and GU operations were enrolled. Patients were randomly allocated into povidone iodine irrigation group (1% available iodine) with normal saline irrigation group. Wound was irrigated with given solution in both the groups, in 60 seconds during operation. Wound were categorised based on their degree of contamination. The rate of wound infection was less in the povidone iodine group compared to normal saline group.

The treatment group did not have untoward effects on wound healing.

Singh and colleagues7 examined 90 patients in a prospective comparative study. In this study the subjects who had clean contaminated procedures were grouped into three study arms. Wound irrigation was given with 5 percent povidone iodine, solution of metronidazole incombination with povidone iodine and normal saline. The incidence of SSI was 10 percent each in the first two groups and thirty percent in the third group.

Sindelar and Mason did another clinical tial in which patients undergoing abdominal operations were included. Peritoneal cavity was irrigated with one liter of povidon iodine for 60 seconds prior to abdominal closure in one group. Normal saline was used to irrigated the peritoneal cavity of another group. The incidence of intraabdominal collection was less in the povidone iodine irrigation group compared to the normal saline group One group. There was increase in iodine level in the serum in few patients one day later. However there was no change in the level of thyroxine nor any adverse effects of elevated levels of iodine.

In another clinical trial, de Jong et al compared the efficacy of wound irrigation with povidone Iodine with no wound irrigation in patients who had abdominal surgeries. The trial was conducted in two phases: 1% povidone Iodine in phase 1 and 10% povidone Iodine in the second phase. There was no statistically significant difference in the treatment arm and the control arm. There was no risk identified.

In another RCT at Limerick Regional Hospital, Tighe and colleagues included 131 patients undergoing appendectomies. The patients were distributed among three arms. The patients received povidone Iodine irrigation intraperitoneally and also on the wound in the 1st arm. In the second arm, the patients were irrigated with sterile water and the third arm got no wound

irrigation.There were no significant differences between the 3 groups. There were no identified complications.

Rogers and colleagues conducted a clinical trial at Nashville Veterans Administration Hospital on patients having general surgery operations. The surgical wound was classified based on the level of contamination. On seeing the subjects for a period about 4 weeks, it was found that the rate of SSI was nuch lesser with the treatment arm. No risk was identified.

Johnson et al performed a clinical trial to study the effect of perineal wound irrigation with povidone Iodine post operatively, on patients who underwent APE for rectal cancer. The treatment group received wound irrigation with povidone Iodine and the control arm received NS wound irrigation.There was statistically significant decrease in SSI rates in the study arm compared with the control arm. Also the wound healing of the abdominal wall was better in the treatment arm even though some of them developed abdominal wall sinus which was not statistically significant.

A randomised trial conducted by Parker et al on patients who underwent major colonic operation for cancer. The treatment arm was given wash with povidone Iodine solution and the control arm received wash with sterile water. The rate of SSI in treatment arm was very less compared to the control arm with statistical significance.

An RCT by Sindelar and colleagues on subjects who at presentation had contaminated abdomen. Intraperitoneal irrigation was given in both the treatment group and the control group; the treatment arm with povidone Iodine solution suctioned 1 minute after irrigation and the control arm with normal saline. There was more incidence of intra abdominal complications in control arm than in treatment arm which was statistically significant. There was abnormal wound healing in both the groups which were not statistically significant. The Iodine levels in the blood were elevated in the povidone Iodine wash group 1 day after

operation which became normal in 1 week. However, there was no systemic toxicity due to increased Iodine levels.

Efficacy of povidone-Iodine irrigation in cardiovascular surgery

Angelini et al performed a comparative research on patients who underwent repeat sterna operation for secondary haemorrhage in the early post operative period. The treatment arm received irrigation with povidone Iodine and the control arm had no wash. There was statistically significant difference in the rate of sternal operation site infection between the groups, with rate of SSI being less in the treatment group.

A randomised trial conducted by Ko along with his colleagues on patients who underwent sternotomy for cardio pulmonary operation.performed a single-blinded RCT on 1980 adult patients who underwent cardiopulmonary bypass surgery with a sternotomy. The treatment arm received irrigation with povidone Iodine and the control arm had normal sasline wash. There was no statistically significant difference in the rate of sternal operation site infection between the groups, even though the rate of SSI was less in the control group.

Efficacy of povidone-iodine irrigation in orthopaedic surgery

There were 2 Randomised controlled trials on patients receiving wash with povidone-Iodine in orthopaedic surgery. Cheng et al studied the effect of povidone Iodine wound irrigation on SSIs in spinal operations. The treatment arm received irrigation with povidone Iodine and the control arm had nomal saline wash. There was statistically significant difference in the rate of deep surgical site infection between the groups, with rate of SSI being less in the treatment group. The difference in the incidence of superficial SSI was not statistically significant.

There was another randomised trial by Chang at al assessing the effect of povidone Iodine wound irrigation on SSIs in spinal operations. The treatment arm received irrigation with povidone Iodine and the control arm had normal saline wash. There was statistically

significant difference in the rate of deep surgical site infection between the groups, with rate of SSI being less in the treatment group. The difference in the incidence of wound dehiscence was not statistically significant. Also there was no statistically significant difference between the two groups in the rate of other post operative complications like increased pain, spinal fusion, wound healing etc.

Efficacy of povidone-iodine irrigation in urologic surgery

Richter and colleagues investigated in a prospective comparative study the effect of povidone-Iodine wound wash in urology patients who underwent open prostate operations. The patients in treatment arm were recruited in the first 6 months of the study and they received wash with povidone Iodine and patients in control arm were recruited in the next 6 months of the study and they received normal saline wash. There was statistically significant difference in the rate of deep surgical site infection between the groups, with rate of SSI being less in the treatment group. None of them had identifiable risks.

Risks of povidone-iodine irrigation

The adverse effects of povidone Iodine surgical site and peritoneal wash was studied by Strife et al on a 15 years old female who underwent abdominal operation for severe PID. She was given peritoneal wash with copious amount of povidone Iodine. There was elevation of SGOT associated with protein loss in urine and microscopic presence of blood in urine after one day of operation. There was also elevation of levels of Iodine in urine and serum upto 3 days post operatively. However,toxicity due to Povidone-Iodine was not demonstrated in this patient.

There is case series which proves that povidone-Iodine may cause thyroid function to get suppressed transiently in premature babies who underwent intestinal anastomosis and the author opined that their thyroxine levels be tested after 2 weeks post operatively.

The major dangers associated with washing the wound or the peritoneal cavity with

povidone-Iodine were related functioning of thyroid in all these studies. Different events have been recorded, however there was no life threatening adverse effect reported. Occasionally, unsterile povidone-Iodine solution can result in development of infectious complications and so utmost care must be ensured that it is sterile before use. When topical povidone-Iodine is used in burns patient, it can result in severe metabolic acidosis owing to the absorption of Iodine. Thus, when the ointment is used on patients with large burns wound and in patients with renal dysfunction, extreme care and precautions must be taken. Povidone-Iodine wash is best avoided, in general, in patients with thyroid disease, renal disease, Iodine sensitivity or burns until more evidence is available..

Based on these studies, it can be concluded that povidone-iodine surgical site or peritoneal irrigation may be useful in reducing the rate of SSIs. The safety profile is still not entirely clear and more studies are necessary to determine if povidone-iodine is the “ideal” solution for irrigation.

The various methods and solutions used for cleaning the wound

For many years and centuries surgical wounds are being cleaned and washed with various techniques and solutions, so as to hasten wound healing. After the advent of antiseptic since Lister's time, they are being used as irrigation agents. Owing to their toxicity and poor effects on wound healing, normal saline has been used as an alternative recently. Wound irrigation rather than swabbing is suggested since swabbing of the wound can damage the epithelialising tissue.

The practice of wound cleansing

Low-pressure irrigation of the wound, usually normal saline in a syringe, is the recommended method of cleaning in the recent times and studies to prove the practice should be assessed.

All the surgical wounds do not need cleaning. Miller and Dyson found cleansing the wound to be not useful since it can hinder wound healing. Wounds which are healing by secondary intention needs cleansing only to excise the debris and superficical slough, excess exudates to be removed and it is not useful in removing bacteria.

Flanagan stated that the benefits of washing the wound were to:

-Assessing the wound

-Hydrate the wound so as to give an environment which is moist

- Minimize injury to the tissues while removing dressing materials

However, rehydration can be achieved using dressings which can retain the moisture and

many interacting agents are used in the modern dressings (Ballard & Baxter, 2000) so as to provide ideal surrounding for cell growth. Interactive agents aim to alter the wound bed in order to promote a suitable environment for cell migration and growth (Ballard and Baxter, 2000).

The evidence for irrigation

According to Towler (2001),wound management has been based upon the expert opinion rather than evidence-based since good RCTs are less in number. So, other means of evidence like case reports, retrospective or prospective observational or case-control studies have to be relied upon for managing the wounds. Level 1 evidence is required to authoritatively implement the methods of wound cleansing.

The principle of wound cleansing is that flushing the wound help in removing the debris and excessive fluids in the surface of wounds. Irrigating the wounds means to flush the wound with the given solution. The important components of wound irrigation are the volume of the solution and the pressure in which it is administered on to the wound so as to make optimum healing environment. The optimum pressure in which the wound debris can be removed has been suggested by Fletcher at al, to be 4-5 psi. A higher pressure will cause damage to the wound and can result in bacterial translocation and so harmful effects. On the other hand, a lower pressure will not have any effect other than wetting the wound.

The most common instruments used for irrigation are syringes and needles which are very much available in the surgical wards. Other equipments which have been suggested for wound wash are shower head, spraying canisters and ampoules which are semi rigid. These instruments reduce the incidence of needle stick injuries also.

Irrigation of wounds must happen in a sterile environment and approximately 250-500 ml of the given solution is recommended for effective wound cleansing.

Choice of cleansing solution

Options of solutions used for irrigation can be ranging from antiseptics to tap water. Some of the antiseptics are potential carcinogens are hence are best avoided (Mallet and Dougherty, 2000).

According to Flanagan (1997)an ideal solution for cleansing the wound require the following features

- Non-toxic to human wound tissues
- Remains effective when organic material is present
- can reduce the burden of mcrobes
- should not yield to allergic or hypersensitivity
- Can be bought easily and less expensive
- should not be a unstable solution with short half life.

According to Lawrence, the antibacterial effects of irrigation of wound is mainly due to the physical action on the tissue and not the antibacterial effect of a given solution.

Inspite of the presence of supporting evidence for normal saline as an ideal irrigant solution, conclusive research is not available and so an ideal irrigation solution is still not clear.

Normal saline wound irrigation done in other operations

A randomised study was conducted by Güngördük K, et al in Mardin Women and Children Hospital, Mardin, Turkey, to find out if normal saline irrigation reduce the wound infection in caesarean delivery or not. The study was conducted on patients who underwent elective and emergency LSCS. The treatment arm received irrigation with normal saline and the control arm had no wash. There was statistically significant difference in the rate of deep surgical site infection between the groups, with rate of SSI being less in the treatment group. There was no difference in the incidence of SSI even after normal saline wash in subjects undergoing LSCS.

Another prospective randomized study was undertaken by Oestreicher M, et al among 540 patients submitted to a general surgical operation. The operative site and the wall before skin closure have been washed either with saline or with Betadine-R solution. Bacteriological samples were taken before irrigation. The contamination rate reached 60% in visceral surgery, 30% in bone surgery. Postoperative wound sepsis nearly reached 6%. There was no difference between the NaCl and Betadine groups.
Hartwich JE, et al. conducted a study to study if saline wound irrigation helps in reducing SSI in paediatric population undergoing appendectomy. Outcome was better(78) with normal saline wound irrigation in appendicitis(79)

Animal study

In guinea pig models, a study was conducted to assess the effect of normal saline prophylactic wash in reducing the SSI. There was significant reduction in the bacterial load at the time of closure of skin and thus the incidence of surgical site infection.

METHODS

Study design

The study was a randomised controlled, double-blinded trial to compare the rate of incisional surgical site infection in wounds which were washed with either normal saline or not washed. The trial was approved by Institutional review board, of our institution. Patients were enrolled after obtaining informed consent. The trial has been registered with CTRI (003197).

Study setting

The study was conducted in the department of general surgery, unit-2 at our institution.

Intervention and Comparator agent:

Normal saline wound irrigation group and

No wound irrigation group respectively**.**

Inclusion Criteria:

All open abdominal elective colorectal surgeries

Laparoscopic surgeries with more than 7 cm long incision

Exclusion Criteria:

1. Abdominal wound is contaminated or dirty at

presentation (pre operatively) e.g. Trauma,

Intra-abdominal sepsis.

2. Layer of skin is not closed.

3. Higher antibiotics are required pre operatively.

Method of randomization:

Computer generated block randomization with block sizes of 2, 4, and 6 at 25%, 25% and 50% respectively.

Method of allocation concealment:

Randomized and sequentially numbered opaque envelopes were opened in the operation theatre just before the skin closure.

Blinding and masking:

Both the investigator and the patient were blinded.

Primary Outcome:

Rate of abdominal incisional surgical site infections (using CDC criteria for incisional surgical site infection)

Secondary Outcomes:

Other risk factors associated (Diabetes mellitus, hypertension, immunosuppression, obesity, anemia, hypoalbuminemia, neoadjuvant chemoradiation, presence of stoma, duration of operation, material used to close skin etc.).

Target sample size and rationale: 226.

Using a retrospective analysis, a sample size of 226 patients (113 in each arm - normal saline irrigation group and no irrigation group) will be sufficient to detect a difference of 15% between the groups in wound infection rate with 80% power and 5% significant levels. 15% difference represents the difference between 10% wound infection rate in normal saline irrigation group and 25% wound infection rate in no irrigation group.

Proportion in No irrigation group	- 0.25
Proportion in Normal saline irrigation group	- 0.15
Risk difference	- 0.1
Alpha error%	- 5
Power %	- 80
Number of comparison groups	- 2
Required sample size for each arm	- 113

Sample size (n) is calculated by the following formula:

$$H_o : P_1 = P_2; \qquad H_a : P_1 \neq P_2$$

$$n = \frac{\left\{ Z_{1-\frac{\alpha}{2}} \sqrt{2\,\bar{P}\,(1-\bar{P})} + Z_{1-\beta} \sqrt{P_1\,(1-P_1) + P_2\,(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Where,

$$\bar{P} = \frac{P_1 + P_2}{2}$$

P_1 : Proportion in the first group

P_2 : Proportion in the second group

α : Significance level

$1-\beta$: Power

Phase of trial:

Phase III clinical trial

Duration of trial:

December 2012 to August 2014

Statistical Analyses:

Data was entered in a epidata.

Comparison of the two groups on surgical site infection rate was done using chi-square test.

Chi-square test for other risk factors was used to identify the independent variable.

Independent sample T test was used for analyzing constants.

Interventions:

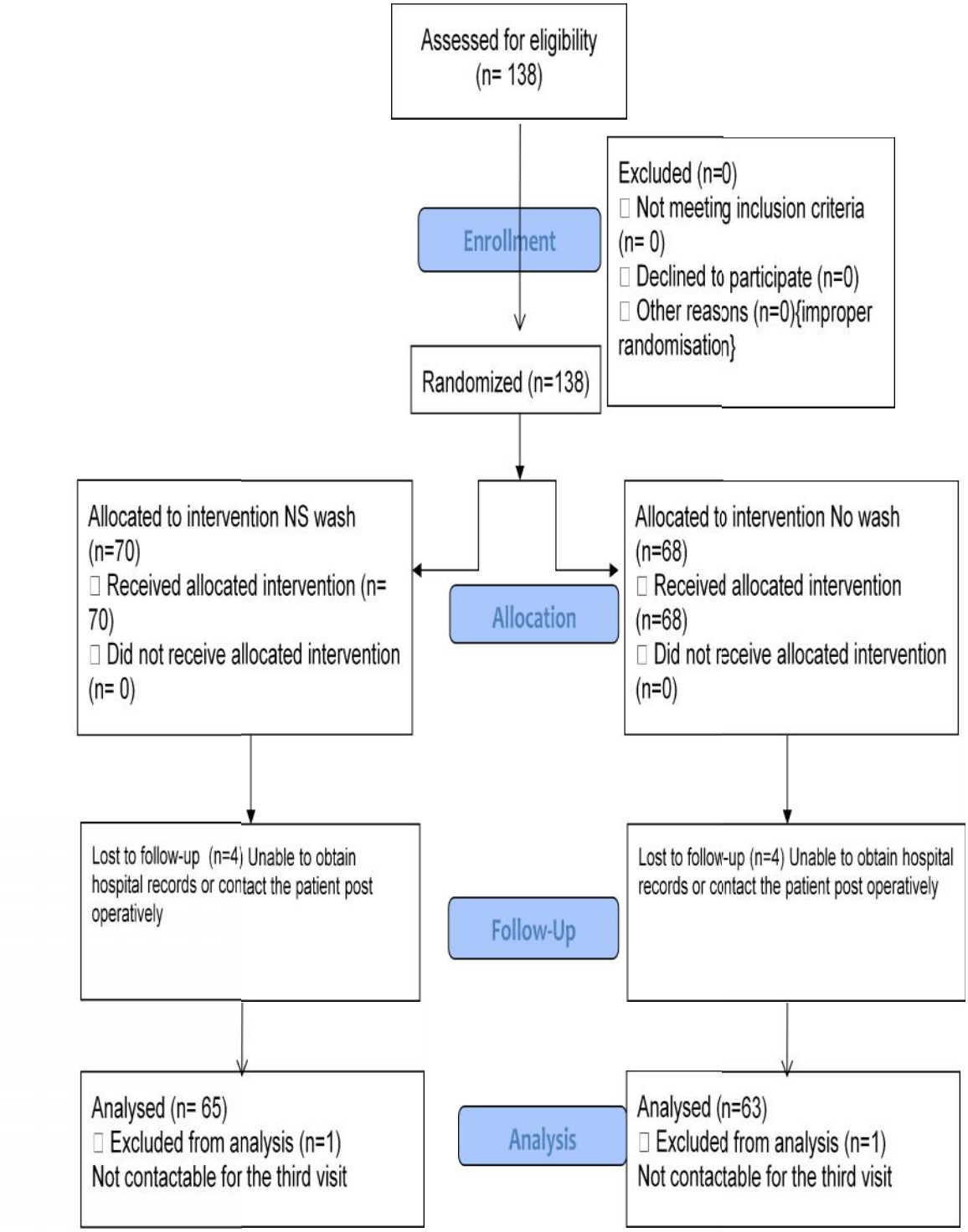
Patients after informed consent were accompanied by a sealed envelope which was allotted to the patients serially. Thus, the patients were randomly allocated to either the treatment group i.e. the normal saline wash group or the control group i.e. No wash group.

The sealed opaque envelopes were opened in the operation theatre after rectus muscle layer was closed and the procedure executed accordingly.

According to the group the patient was allocated to, the procedure was executed.

In the normal saline wash group, freshly opened 500ml normal saline bag was opened and used to irrigate the wound just before closure.

CONSORT STATEMENT OF THE STUDY



Allocated to intervention NS wash (n=70)
Received allocated intervention (n= 70)
Did not receive allocated intervention (give reasons) (n= 0)

RESULTS AND ANALYSIS

AGE DISTRIBUTION:

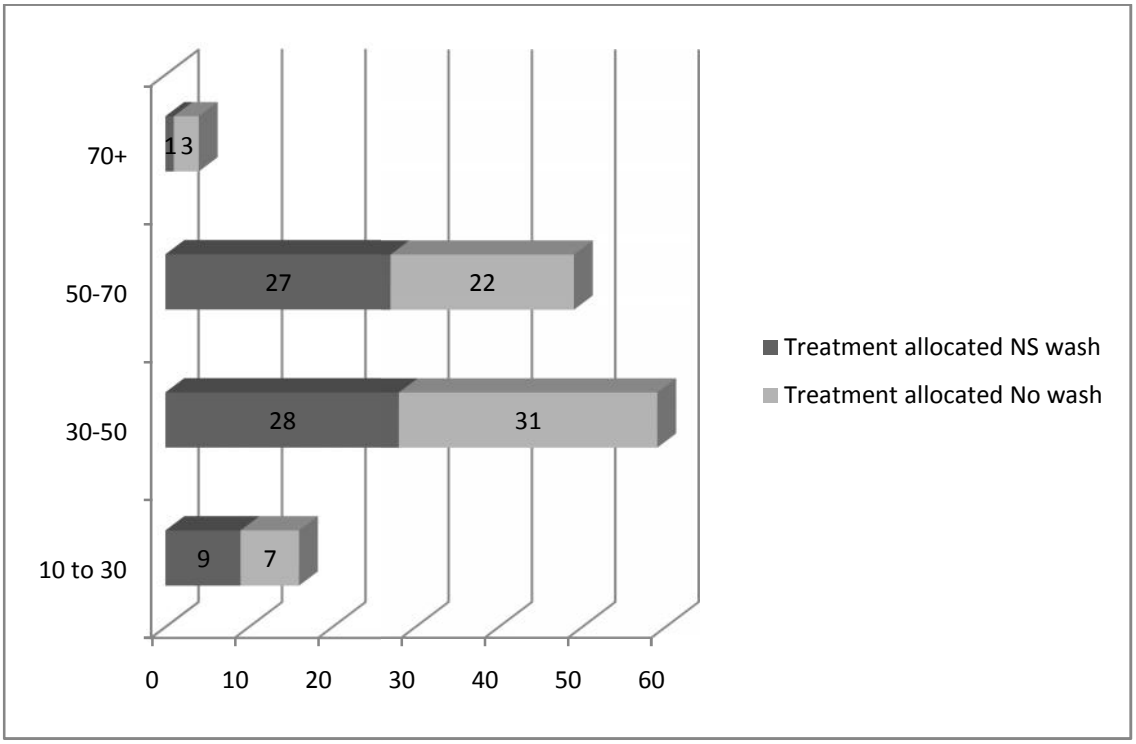


Fig. 1 showing the Age distribution of patients in both treatment and control arms

The mean age among the two arms was comparable.

	N	Mean	Std. Deviation	Std. Error
NS wash	65	46.9	14.08	1.75
No wash	63	47.6	13.38	1.68

Table 1 shows the mean ages in the two arms along with the standard deviation

SEX DISTRIBUTION:

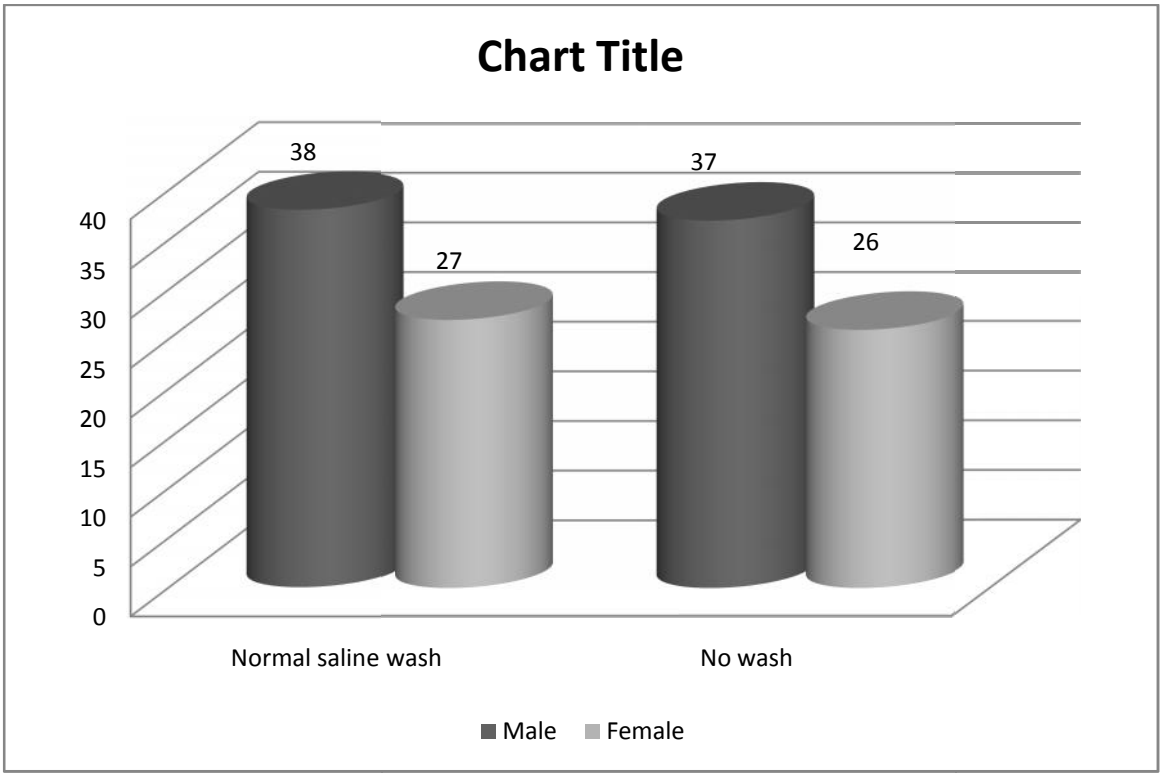


Fig. 2 showing the sex distribution of patients in both treatment and control arms

	NS wash	No wash
Male	38	37
Female	27	26

Distribution of parameters assessed

Parameter	Study arm(NS wash)	Control arm(No wash)
DM	12	18
Hypertension	15	12
Obesity	17	14
Anaemia	18	26
Hypoalbuminemia	8	5
Immunosuppression	6	3
Preoperative Chemoradiation	33	22
Presence of stoma	53	50
Operated by consultants	49	45
Chlorhexidine skin preparation	60	59
Transverse skin incision	9	13
Duration of surgery >3 hrs	45	33

All the parameters assessed were equally distributed between the two arms.

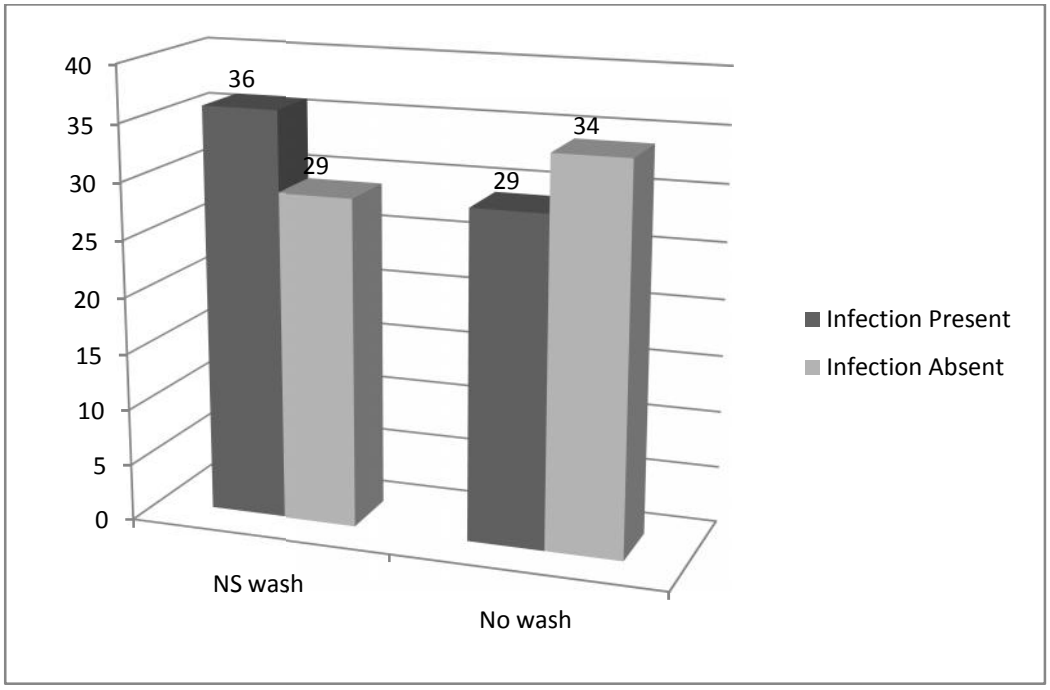


Fig. 3 showing the presence of infection among patients in both treatment and control arms

	NS wash	No wash
Infection present	36	29
Infection absent	29	34

Pearson chi2 = 1.1197 Pr = 0.290

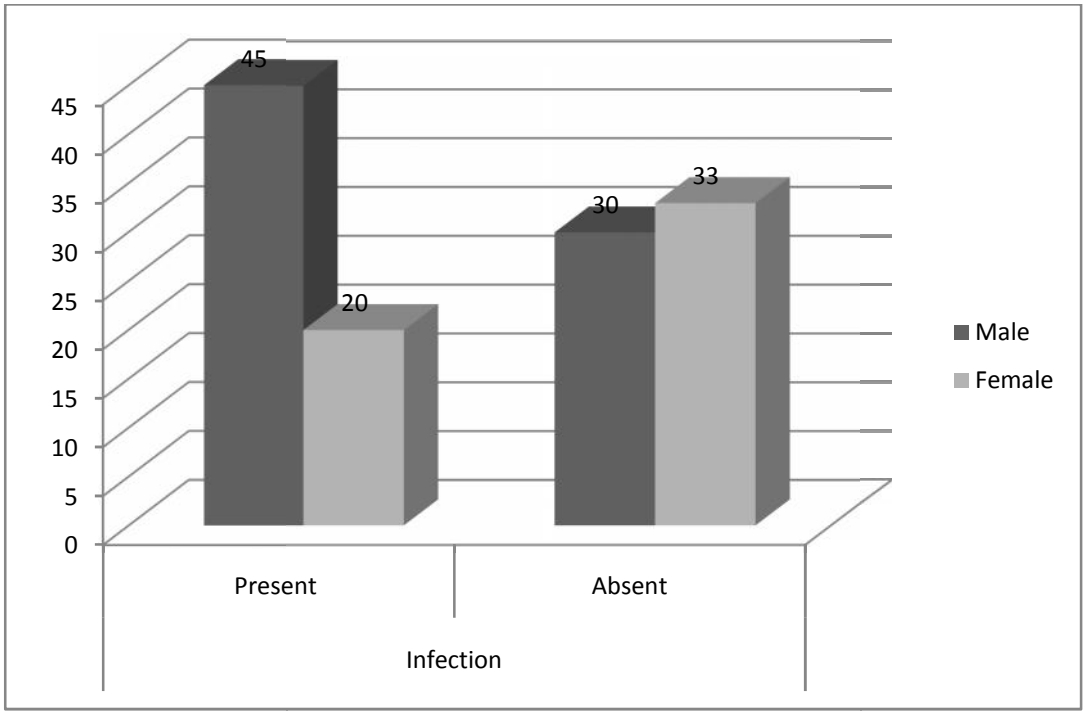


Fig. 4 showing relation of gender and the incidence of incisional wound infection

	Infection	
	Present	Absent
Male	45	30
Female	20	33

Pearson chi2 = 6.1589, P = 0.013

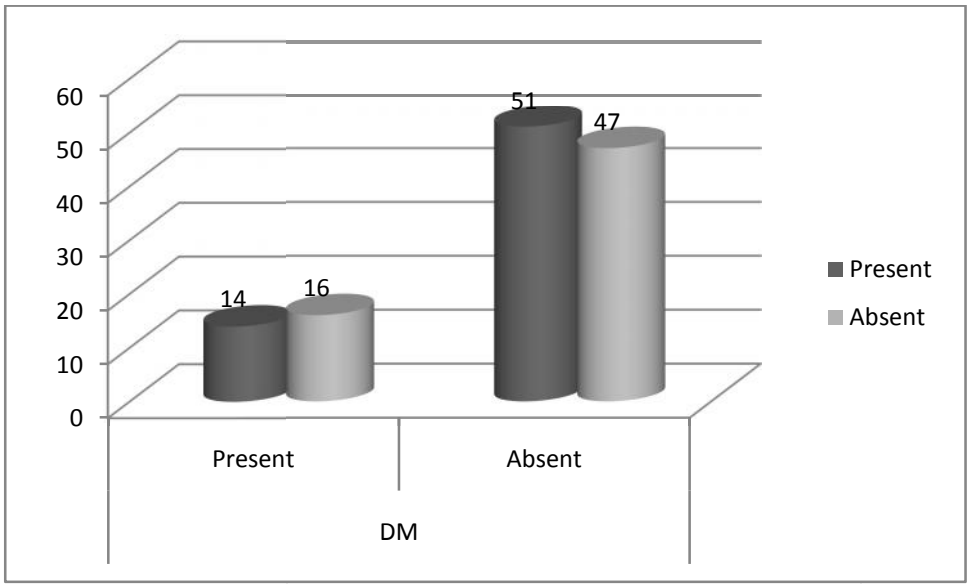


Fig. 5 showing relation between presence of DM and the incidence of incisional wound infection

Infection	**DM**	
	Present	Absent
Present	14	51
Absent	16	47

Pearson chi2 = 0.2654 P = 0.606

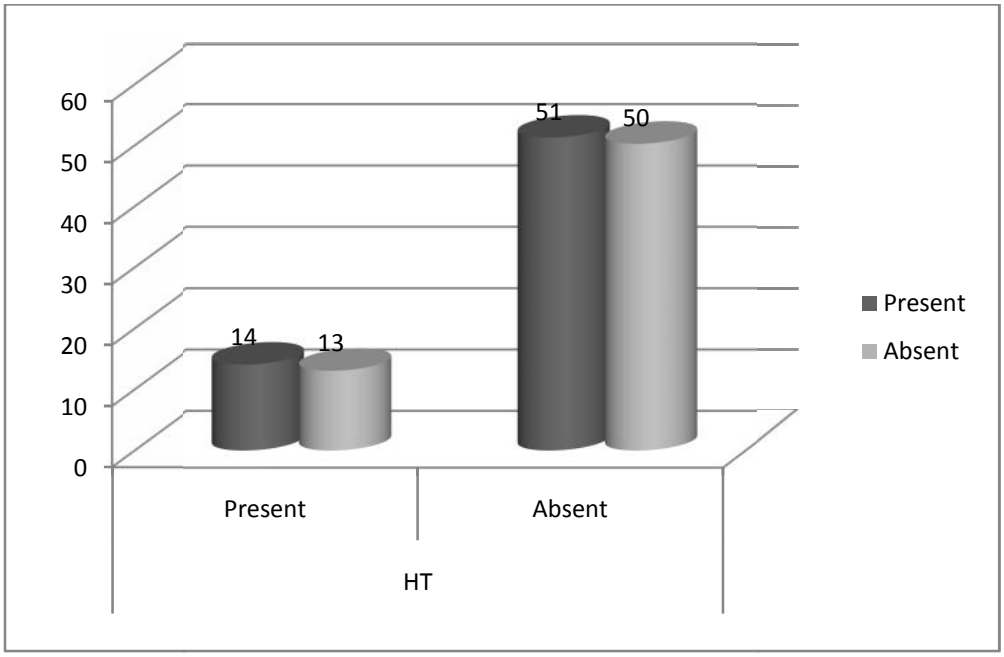


Fig. 6 showing relation between presence of hypertension and the incidence of incisional wound infection

Infection	**HT**	
	Present	Absent
Present	14	51
Absent	13	50

Pearson chi2 = 0.0157 P = 0.900

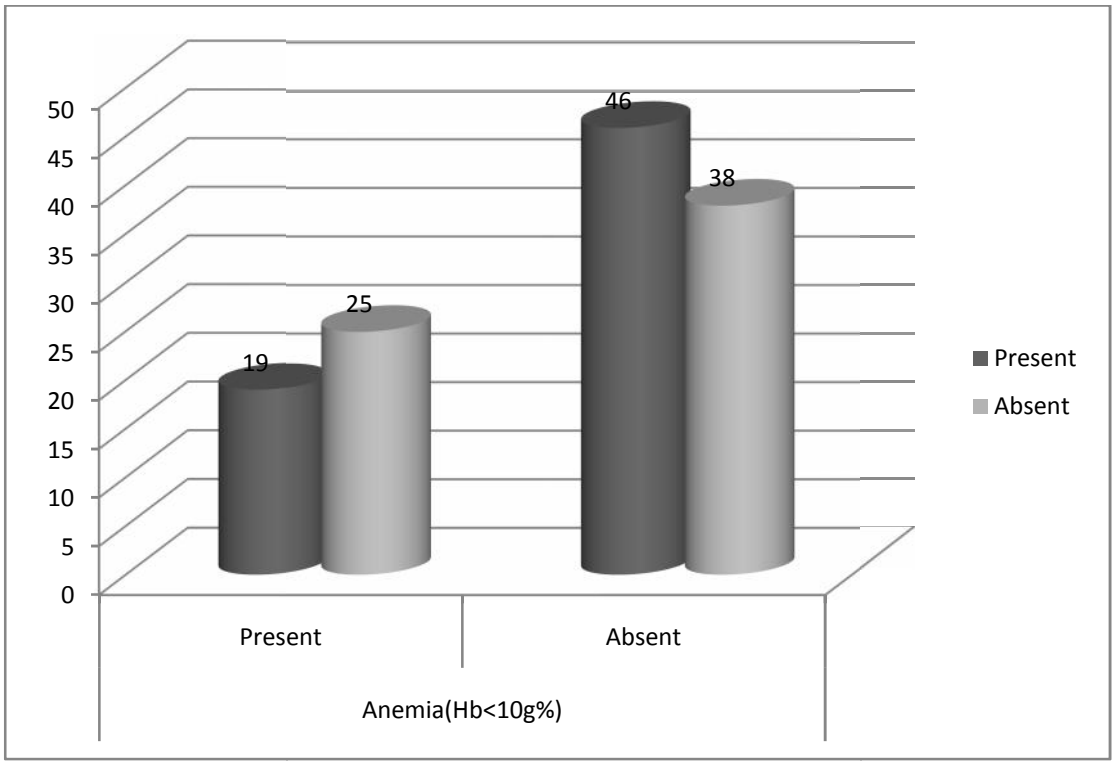


Fig. 7 showing relation between presence of anaemia and the incidence of incisional wound infection

Infection	Anaemia (Hb<10g %)	
	Present	Absent
Present	14	51
Absent	13	50

Pearson chi2 = 1.5492 P = 0.213

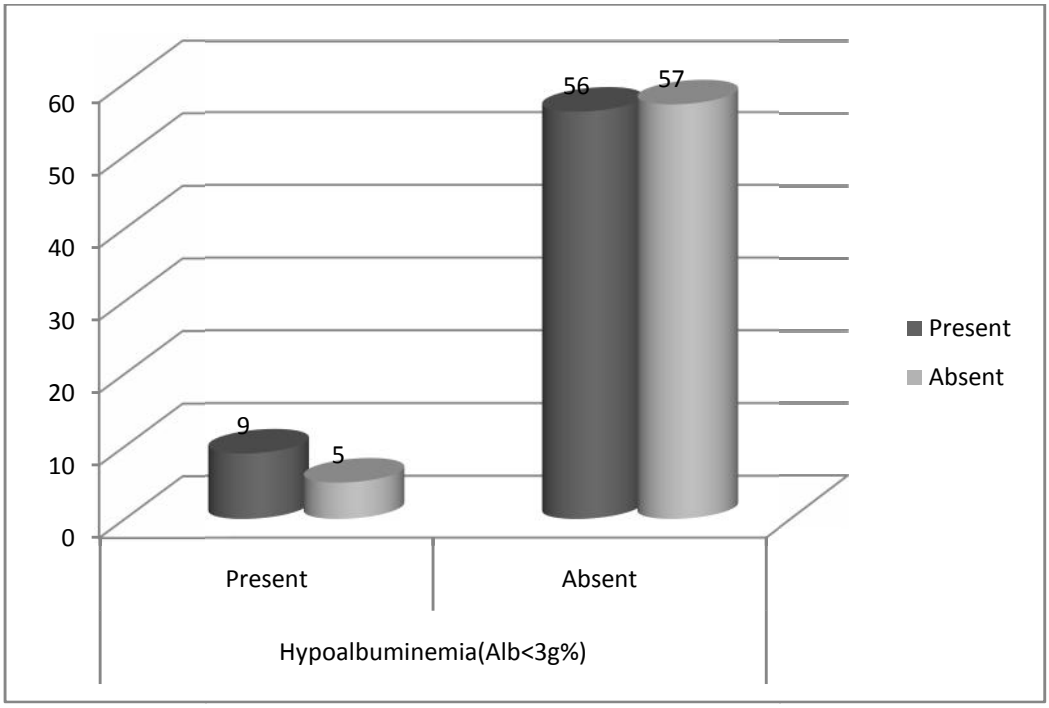


Fig. 8 showing relation between presence of hypoalbuminemia and the incidence of incisional wound infection

Infection	Hypoalbuminemia (Alb<3g%)	
	Present	Absent
Present	9	56
Absent	5	57

Pearson chi2 = 2.8627 P = 0.239

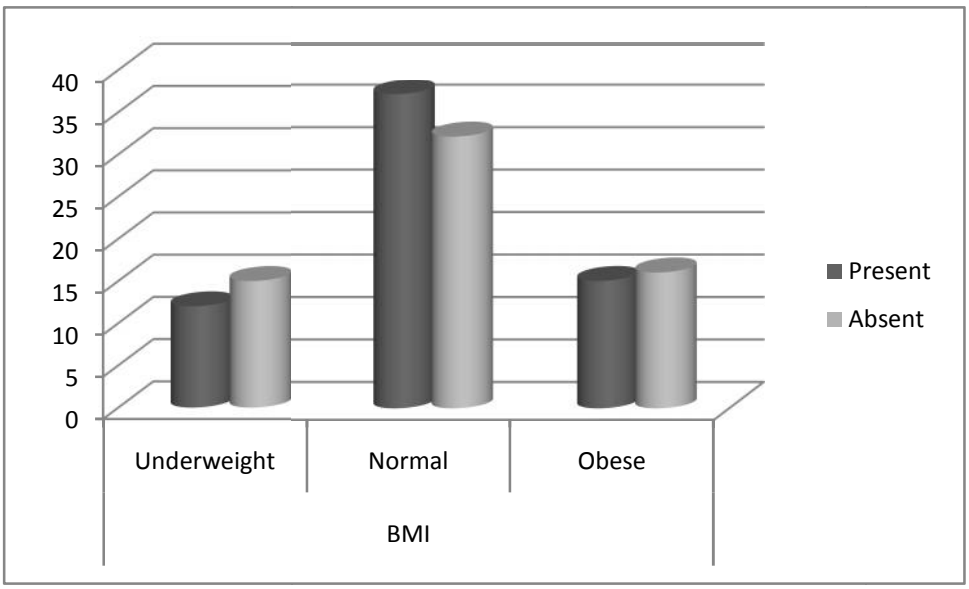


Fig. 9 showing relation between patients with varying BMI and the corresponding incidence of incisional wound infection

Infection	**BMI**		
	Underweight	**Normal**	**obese**
Present	**12**	**37**	**15**
Absent	**15**	**32**	**16**

Pearson chi2= 0.7201 P = 0.698

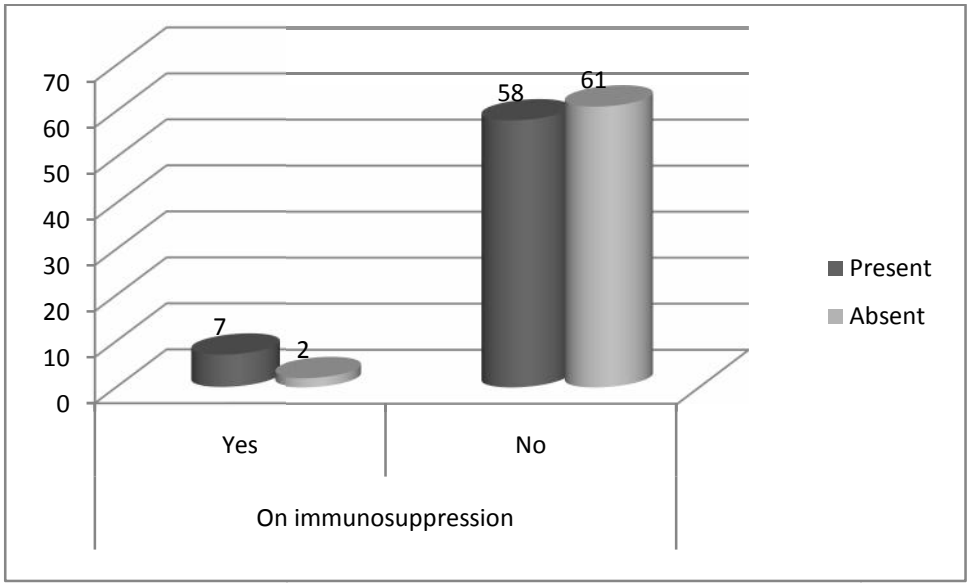


Fig. 10 showing relation between presence of immunosuppression and the incidence of incisional wound infection

Infection	On immunosuppression	
	Yes	No
Present	7	58
Absent	2	61

Pearson chi2 = 2.8228 P = 0.093

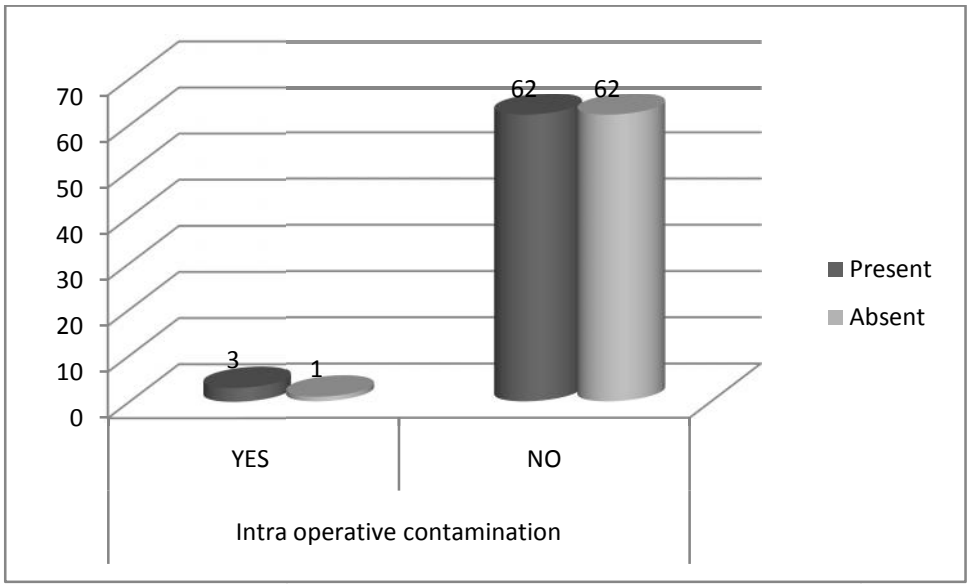


Fig. 11 showing relation between presence of Intra operative contamination and the incidence of incisional wound infection

Infection	Intra operative contamination	
	Yes	No
Present	3	62
Absent	1	62

Pearson chi2 = 0.9690 P = 0.325

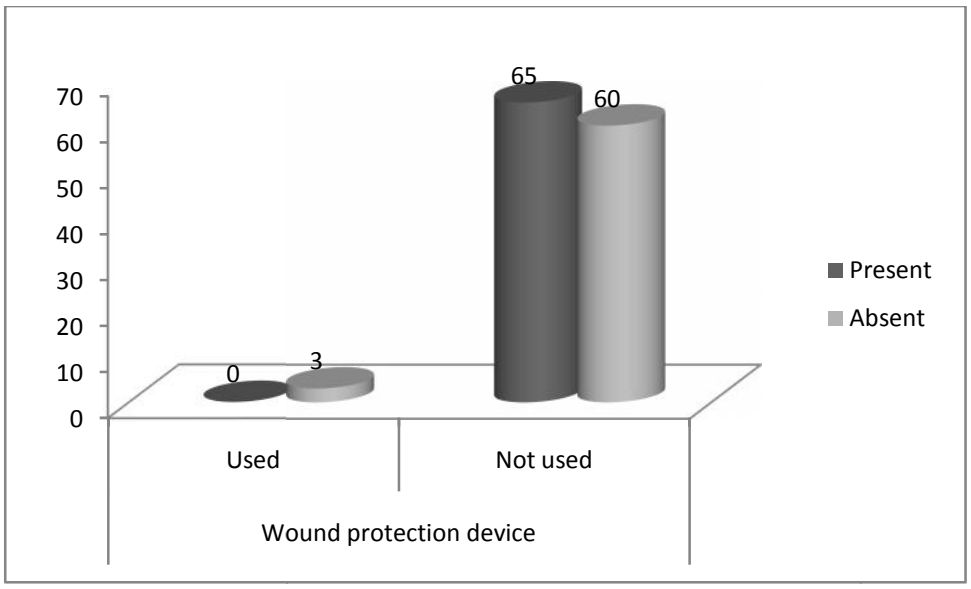


Fig.12 showing relation between usage of wound protection device and the incidence of incisional wound infection

Infection	Wound protection device	
	Used	Not used
Present	0	65
Absent	3	60

Pearson chi2 = 3.1695 P = 0.075

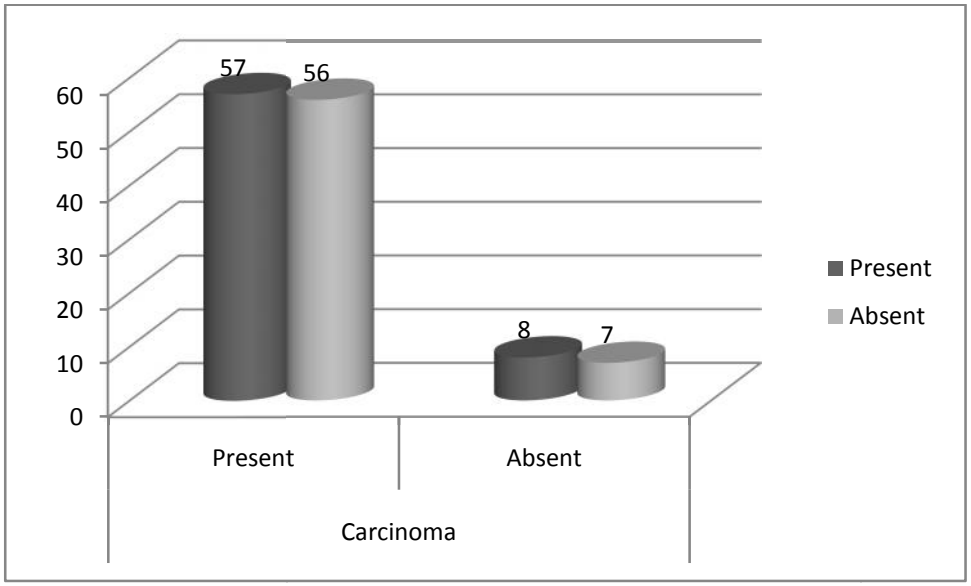


Fig. 13 showing relation between carcinoma and the incidence of incisional wound infection

Infection	Carcinoma	
	Present	Absent
Present	57	8
Absent	56	7

Pearson chi2 = 0.0443 P = 0.833

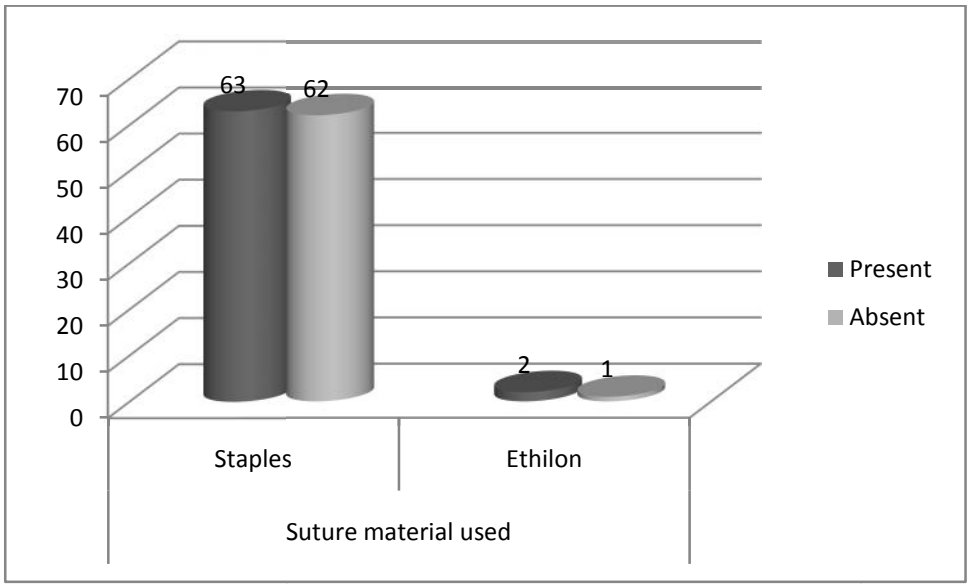


Fig. 14 showing relation between various suture material used and the incidence of incisional wound infection

Infection	Suture material used	
	Staples	Ethilon
Present	63	2
Absent	62	1

Pearson chi2 = 1.3024 P = 0.521

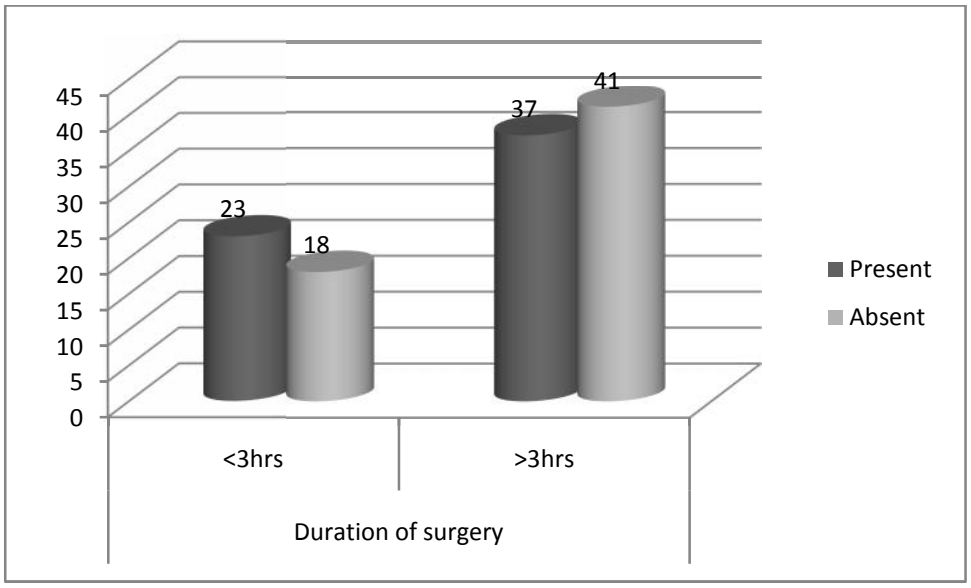


Fig. 15 showing relation between duration of surgery and the incidence of incisional wound infection

Infection	Duration of surgery	
	<3hrs	>3hrs
Present	23	37
Absent	18	41

Pearson chi2 = 0.8065 P = 0.369

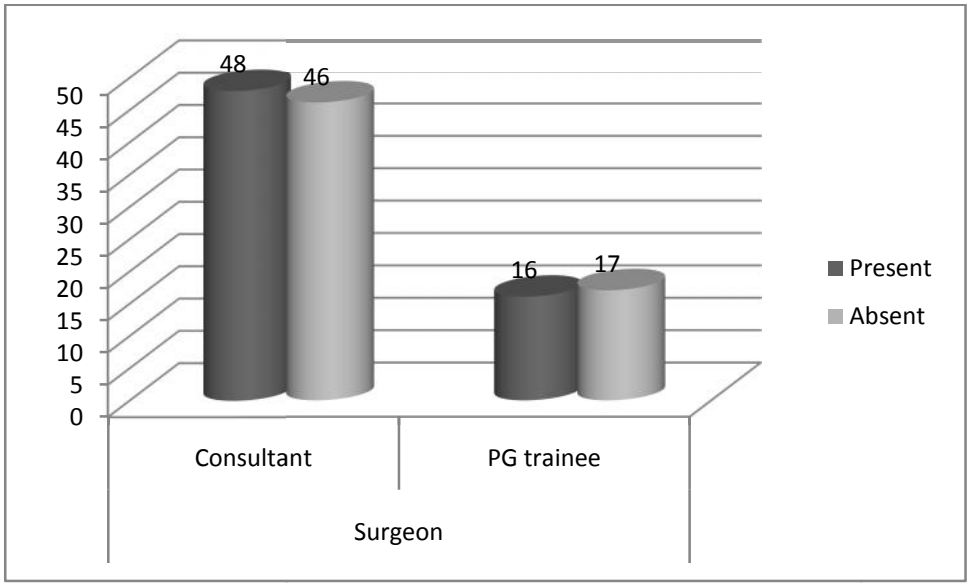


Fig. 16 showing relation between experience of the operating surgeon and the incidence of incisional wound infection

Infection	Surgeon	
	Consultant	PG trainee
Present	48	16
Absent	46	17

Pearson chi2 = 0.0650 P = 0.799

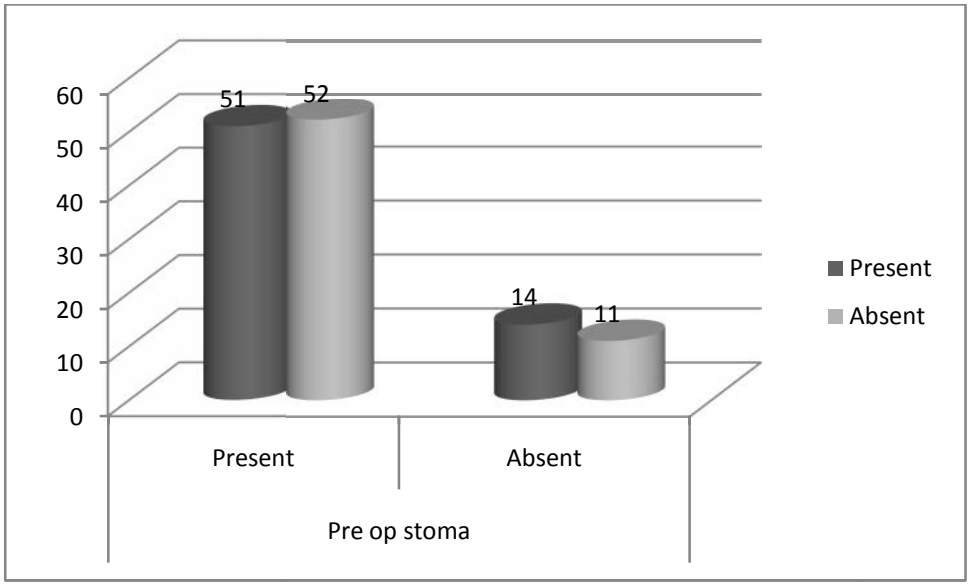


Fig. 17 showing relation between presence of pre operative stoma and the incidence of incisional wound infection

Infection	Pre op stoma	
	Present	Absent
Present	51	14
Absent	52	11

Pearson chi2 = 0.3385 P = 0.561

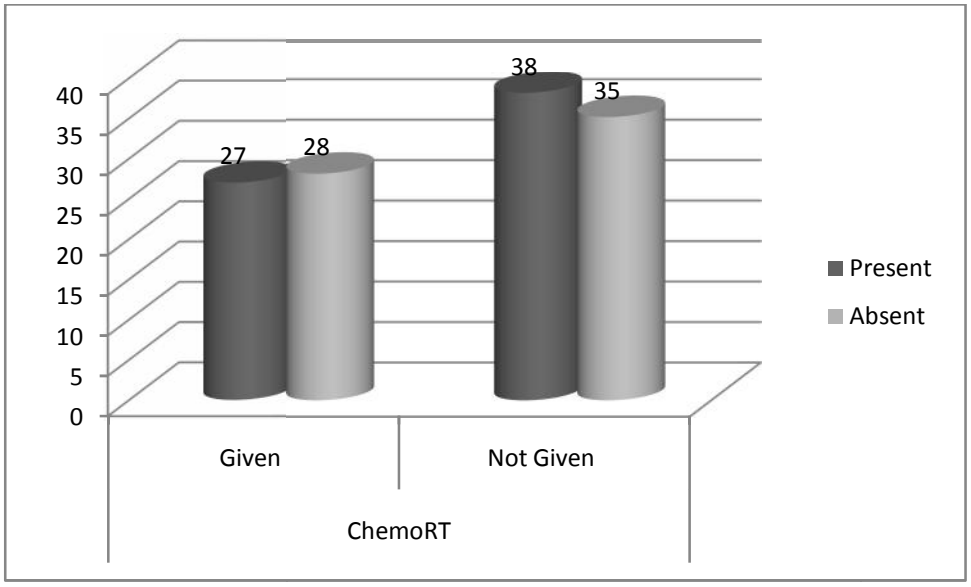


Fig. 18 showing relation between preoperative chemoradiation therapy and the incidence of incisional wound infection

Infection	ChemoRT	
	Given	Not Given
Present	27	38
Absent	28	35

Pearson chi2 = 0.1102 P = 0.740

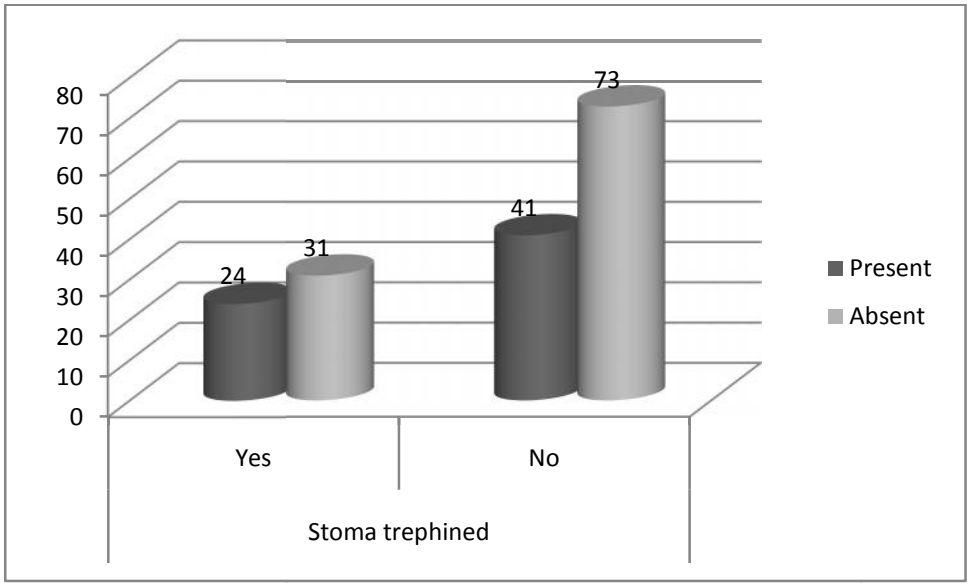


Fig. 19 showing relation between new stoma created and the incidence of incisional wound infection

Infection	Stoma created	
	Yes	No
Present	24	41
Absent	31	73

Pearson chi2 = 1.9697 P = 0.160

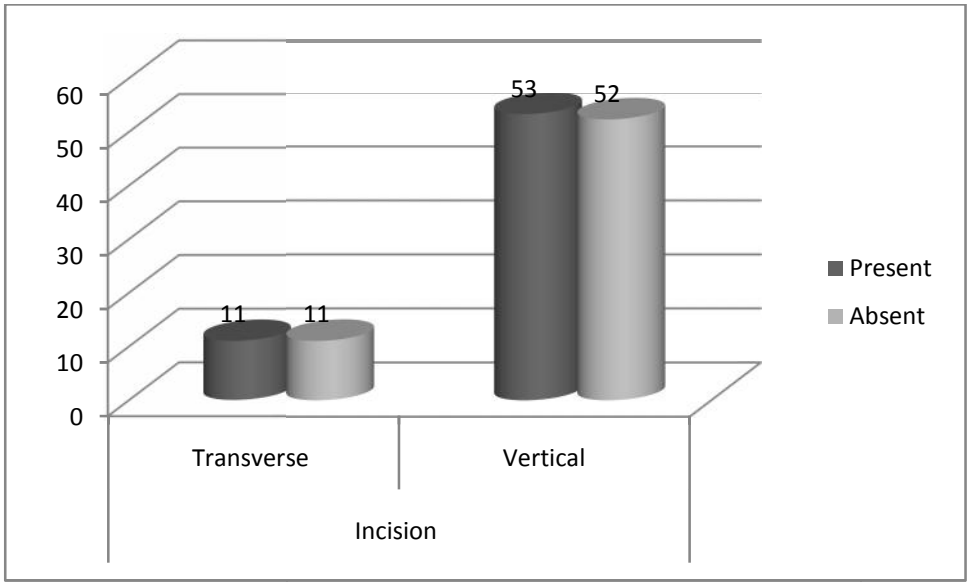


Fig. 20 showing relation between incision and the incidence of incisional wound infection

Infection	Incision	
	Transverse	vertical
Present	11	53
Absent	11	52

Pearson chi2 = 0.0016 P = 0.968

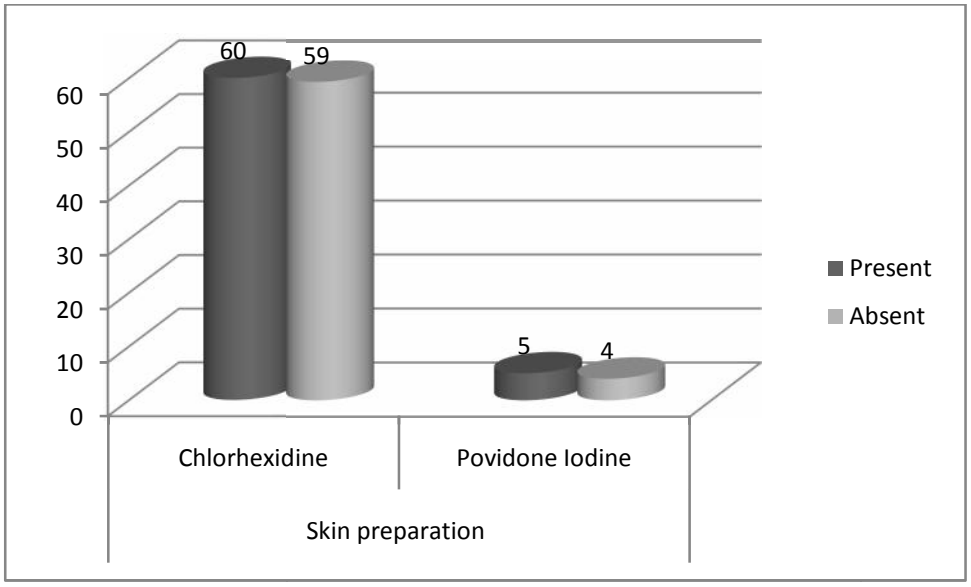


Fig. 21 showing relation between skin preparation and the incidence of incisional wound infection

Infection	Skin preparation	
	Chlorhexidine	Povidone Iodine
Present	60	5
Absent	59	4

Pearson chi2(1) = 0.0883 Pr = 0.766

RESULTS

A total of 138 patients were included in this trial, out of which 10 patients were lost to follow up at the last visit. Among the rest of the patients, 65 were randomised to the treatment arm i.e. Normal saline wash group, and 63 were included in the No wash group.

A total of 128 patients were included in the statistical analysis.

Out of the total of 128 patients, 84 were males which are consistent with the international statistical figures. The male: female ratio was found to be 1.9:1.

Colorectal diseases were more prevalent among the age group 30-50 and there was equal distribution of patients among both the intervention arms in all the age groups.

Almost 88% of the patients had a diagnosis of malignancy and others had benign colorectal diseases like inflammatory bowel disease, tuberculosis etc.

Most of the patients were geographically from Bangladesh and West Bengal followed by TamilNadu and Andhra Pradesh.

The incidence of incisional SSI was found to be 55.38% in the treatment arm and 44.62% in the control arm. The overall incidence of incisional surgical site infection in colorectal operation during the period December 2012 to August 2014 was 50.78%

Fig. 5 shows relation between presence of DM and the incidence of incisional wound infection. Diabetes mellitus was present in 23.44 % of the study population and 14/30 patients had developed incisional SSI.

Fig. 6 shows relation between presence of hypertension and the incidence of incisional wound infection. 21.09% of the study population had systemic hypertension and 14/27 developed infection post operatively.

Also found were associated risk factors like anaemia, hypoalbuminemia, obesity, presence of immunosuppression, presence of stoma pre operatively or post operatively, chemo radiation therapy etc.

Intra operative factors like the experience of the surgeon, skin preparation solution used, wound protector devices, duration of surgery, creation of a new stoma, suture material used to suture the skin and presence of intra-operative faecal contamination were also considered to find out whether they affect the incidence of incisional surgical site infection.

DISCUSSION

There is high morbidity and mortality related to incisional surgical site infections following colorectal surgery. Colorectal resections themselves are associated with higher morbidity and morbidity and mortality compared to other abdominal operations.

As we have noticed in this study, the large group of patients undergoing colorectal operations have malignancy as their primary diagnosis.

There is male predominance with a male to female ration of 1.9:1, and more males have been included in our study. The age distribution of the colorectal diseases follows a normal distribution. There was more prevalence of colorectal diseases among the age group 30-50 years and there was equal distribution of patients in both the intervention arms in all the age groups.

Out of the total of 128 patients, 65.6 %(n= 84) were males which is consistent with observations from other centres around the world.

Almost 88 %(n=113) of the patients had a diagnosis of malignancy and others had benign colorectal diseases like inflammatory bowel disease, tuberculosis etc.

The overall incidence of incisional SSI in open colorectal operations during the period December 2012 to August 2014, at the department of general surgery2, Christian Medical College Vellore, was 50.78%.

The incidence of incisional surgical site infection following open colorectal surgery has been reported to range from 5% to 26% [4–8].

The incidence of SSI for colon surgery was 15.0% (6,691 of 44,751) and rectal surgery was 17.8% (3,230 of 18,187) in a retrospective nationwide Japanese surveillance-based study.

Most of the variation in the incidence of incisional SSI is probably due to modification of CDC definitions of SSI and inter-observer variation among differing personnel carrying out the assessments for infection. In this study strict CDC definitions were adopted.
Some of these studies include also the laparoscopic surgeries rather than just open colorectal operations which has a much lesser incidence of surgical site infections

The degree of contamination of the surgical wound with bacteria is fundamental to the risk of onset of SSI. We hypothesized that in a colorectal operation, because of the heavy bacterial load of colon and rectum, the procedures of anastomosis were associated with faecal contamination at the surgical site and so there was increased chance of developing wound infection, if the patient has undergone end-to-end anastomosis for various types of colectomy and for rectal anterior resection in comparison with no anastomosis in abdomino-perineal resection and in Hartmann's operation.

However, Konishi and colleagues have reported that the rate of SSI was lesser in colonic operations compared to rectal operations . This is because operation for rectal malignancy involves creation of stoma, long course neoadjuvant chemoradiation therapy along with total mesorectal excision and anastomosis close to anal verge. These factors possibly lead prolonged operation and can cause higher bacterial contamination. Bacterial contamination was the basis of improving the incidence of incisional surgical site infection by normal saline wound irrigation.

The incidence of incisional SSI was found to be 55.38% in the treatment arm and 44.62% in the control arm. This result is in contrast to the expectation that Normal saline wound irrigation will help in reducing the surgical site infection. However, due to lack of adequate numbers, it is not possible to draw any definite conclusion from the above observation and there is need for larger sample size to show adequate statistical difference between the two arms, the normal saline wash arm and the no wash arm.

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Other risk factors which were assessed were

Demographic factors:

Age and sex

Pre operative factors:

Primary diagnosis as malignancy

BMI

Diabetes mellitus

Systemic hypertension,

Anaemia

Hypoalbuminemia

Immmunosuppression

Presence of stoma pre operatively

Neoadjuvant chemoradiation therapy

Intra operative factors studied were:

Experience of the operating surgeon

Skin preparation used

Duration of surgery

Intra operative contamination

Wound protectors

Suture material used for skin

Stoma creation at the end of the operation

Even though there were differences in the number of patients who developed incisional SSI between the groups, this difference was not statistically significant, with p value more than 0.05 in all these parameters. There is a necessity of a larger sample size to determine a statistically significant difference and thus draw conclusions regarding their association with the incidence of SSI.

CONCLUSIONS

1. There was no significant difference observed in the rate of SSI between patients whose wounds were irrigated with normal saline and those whose wounds which were not. However, the sample size was not reached and therefore no conclusion can be derived. It is planned to continue the study till the sample size is reached.

2. The incidence of incisional SSI in patients who underwent elective open colorectal operations in our institution was higher compared to the incidence reported in other studies in the world. This could be due to lack of uniformity in the and to diagnose SSI.

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3. Other factors which might play a role in the development of surgical site infection were also studied. However, none of them showed definite association.

LIMITATIONS:

1. It was a time bound clinical trial conducted in a single centre and so there is paucity of data.

2. There was no prescribed pressure at which the irrigation was to be performed. This could be an important factor.

3. The interim analysis of a clinical trial might not depict the entire picture of the intervention.

POTENTIAL FOR FURTHER RESEARCH

It is an ongoing challenge to prevent wound infection in elective colorectal operations. There is a trend towards laparoscopic colorectal operations from open procedures which will imply shorter hospital stay, smaller incisions and development of surgical site infection will be less severe, less frequent and less intense in the superficial and deep compartments of the abdominal wall. Organ or space surgical site infection will continue to be a potential source of mortality and morbidity. SSI needs to be standardized as for surveillance methods and definitions are concerned, which will help clinicians to assess the wounds objectively.

Thus, it requires a continuous and prolonged use of all the techniques and methods which are accepted to reduce the wound contamination intra operatively and a close monitoring of the preventive measures for conditions of the surgical site that promote wound infection.

Newer techniques have to be discovered to decrease surgical site infection in colorectal operations. It seems unlikely that further advances in the field of microbiology (in the form of systemic antibiotics) will improve the results. The methods could be aiming at a physiological optimal condition in the patient by maintaining homeostasis, normothermia, intra-operative supplemental oxygen and good glycemic control. It seems appropriate to use wound protection device while extracting specimen to avoid contact of the specimen with the surgical site.

ANNEXURES

PROFORMA

(A randomised controlled trial comparing the post operative abdominal surgical site wound infection in patients who are given an intra operative normal saline irrigation with the patients who are not given any irrigation)

Serial no.:

Name : Age : Sex: Hospital No.:

Address : Contact No:

PRE OPERATIVE:

Primary Diagnosis:

Weight(in Kg): Height(in cm): Body mass index(wt/ht^2):

Co-morbidities :

1. Diabetes mellitus - Yes/No
2. Hypertension - Yes/No
3. Haemoglobin <8 g% - Yes/No
4. Albumin <3 g/dL - Yes/No
5. On immunosuppressants - Yes/No
6. Chemo radiation - Yes/No
7. Stoma present - Yes/No

Operation performed :

Elective / Emergency :

INTRA-OPERATIVE PERIOD:

Surgeon : Consultant / PG trainee

Pre-operative antibiotic used :

Skin preparation : Chlorhexidine / Povidone Iodine

Incision made : Transverse / Vertical

Length of incision (in cm) :

Any intra operative contamination : Yes/No

Wound protection device used : Yes/No

Duration of surgery (in hrs and min) :

Skin closed : Yes/No

Suture material used for skin closure :

Stoma trephined: Yes/No

POST OPERATIVE PERIOD

Antibiotics used : Yes/No

If yes, what antibiotics

Post operative complications : Yes/No

If yes, the event (Anastomotic leak /LRI /UTI /Others) :

(6) Wound assessment	**Till discharge**	**1st OP visit 14-16 days**	**1st month**
Symptoms :			
Pain : Yes/No			
Swelling : Yes/No			
Discharge : Yes/No If yes, serosanguineous/pus/others:			
Fever : Yes/No			
Signs :			

Tenderness : Yes/No			
Erythema : Yes/No			
Increased warmth : Yes/No			
Wound dehiscence : present / absent			
Sutures or staples removed: Yes/No			
Investigations :			
Pus culture and sensitivity : done / not done If done, Is it significant? Yes/No			
Radiological investigation for deep incisional abscess?			
If reoperation, findings(evidence of infection / abscess):			
Diagnosis of surgical site infection made by the surgeon : Yes/No			

Information sheet

INFORMED CONSENT

Christian Medical College, Vellore
Department of General Surgery

A randomized controlled trial comparing the rate of surgical site infection when normal saline wound irrigation is given and when not given in colorectal resections.
Information sheet

You are being requested to participate in this study to find out if normal saline wound irrigation when given intra operatively, decreases the surgical site infection rate by decreasing the bacterial contamination from the bowel and the skin. We hope to include about 226 people from this hospital in this study.

Does Normal saline irrigation help in preventing surgical site infection?

Any operation carries the risk of wound infection. There are some known factors which affect wound healing and some are not known. It is not known whether normal saline wound irrigation decreases the risk of wound infection or not.

Does Normal saline wound irrigation have any side effects?

Normal saline wound irrigation does not have any proven adverse effect on the wound or the body.

If you take part what will you have to do?

If you agree to participate in this study, you will be either given normal saline wound irrigation or no irrigation at all. Neither you nor your doctor will have any choice in whether you will get normal saline wound irrigation or not as this will be decided by a computer program; this is like tossing a coin and you have an equal chance of getting either treatment. Also, neither you nor your doctor will know which group you belong to till the study is over.

All other treatments that you are already on will be continued and your regular treatment will not be changed during this study. You will be expected to come for a review to the hospital 2 weeks after the operation and again 2 more weeks later. You will be asked questions about your wound, and you will be examined at each visit. You will be asked to do a microbiological test to look for organisms in the wound if wound infection is suspected by your doctor. No additional procedures or blood tests will be conducted routinely for this study.

If at any time you experience any problems, you will be expected to report this to the doctor. You will also be contacted by telephone as and when needed in between your visits by the doctors in this study who will ask you about any symptoms of wound infection you are experiencing.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for normal saline wound irrigation or the culture?

You will not have to pay extra for Normal saline wound irrigation. Any other treatment or investigation that you usually take will continue but the usual arrangements that you have with the hospital will decide how much you pay for this.

What happens after the study is over?

You may or may not benefit from type of treatment you are given. Once the study is over, if the normal saline wound irrigation has helped, we might continue to do the same for our patients on a regular basis. You will not be involved in this.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr.Augustin Abraham.T, Dr. Rohin Mittal or Dr. Mark Ranjan Jesudasan (tel: 0416 2282159/ 2282120/ 2282207) or email: augustin.t@cmcvellore.ac.in

Consent form

CONSENT TO TAKE PART IN A CLINICAL TRIAL
Study Title:
Does Normal saline wound irrigation help in preventing post operative surgical site infection?

Study Number:
Participant's name:
Date of Birth / Age (in years):

I_____
_____, son/daughter of _____

(Please tick boxes)
Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]
I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
I also understand that neither I, nor my doctors, will have any choice or knowledge of whether I will get Normal saline wound irrigation or not [ ]
I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]
I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access
[ ]
I understand that my identity will not be revealed in any information released to third parties or published [ ]
I agree to pay for any investigation routinely warranted for my treatment [ ]
I voluntarily agree to take part in this study [ ]

Name:
Signature:
Date:

Name of witness:
Relation to participant:
Date:

EPI DATA SHEET

Variable name	Label	<IDNUM>
sno S.No.	Study No.	###
DOE	Date of enrollment	<dd/mm/yyyy>
Name	Patient's name	_____
Age	Age in years	##
Sex	Gender	#(1-Male, 2-Female)
ID no.	Hospital No.	######
Contact no.	Mobile No.	###########
Address	Residential	_____ address1
_____		address2
_____		
Wt	In Kg	###
Ht	In cm	###
BMI	Wt/Ht2	##.##
Pre-op		
PDx	Primary Diagnosis	_____
CA	carcinoma	# (1-present, 2-absent)
DM	Diabetes Mellitus	#(1-yes,0-No)
ht1 HT	Hypertension	#(1-yes,0-No)
Hb	Anaemia(Less than 10g%)	#(1-yes,0-No)
Alb	Hypoalbuminemia	#(1-Less than 1.5g%,2-1.5 to 3,3-More than 3.1)
ImmS	On immunosuppressants	#(1-yes,0-No)
CRT	Chemoradiation therapy	#(1-Given,0-Not given)
Stoma	Presence of stoma	#(1-Present,0-Absent)
Operation	Operation performed	
_____		
Type	Type of operation	#(1-Elective,2-Emergency)
INTRA-OP		
Sur	Surgeon	#(1-Consultant,2-PG trainee)
Antibiotics	Pre-operative antibiotics	#(1-Yes,2-No)
Skin Prep	Skin preparation	#(1-Chlorhexidine,2-Povidone Iodine)
Incision	Vertical/Horizontal	#(1-Transverse,2-Vertical)

LOI	Length of incision	#(1-More than 7cm,2-Less than 7cm)
IOPCon	Int-operative contamination	#(1-Yes,0-No)
Device	Wd prt device used	#(1-Yes,0-No)
DuOSx	Duration of surgery	#(1-Less than 3hrs,2-More than 3hrs)
Skincl	Skin closed	#(1-Yes,0-No)
SuMat	Suture Material used	#(1-Staple,2-Ethilon,3-Monocryl)
Stmtr	Stoma trephined	#(1-Yes,0-No)
Post-op		
Abx	Antibiotic used	#(1-Yes,0-No)
If yes	If yes,What	_____
Cmpl	Postop complications	#(1-Yes,0-No)
if1 If yes	If yes,What	_____
Wound assessment till discharge		
Symptoms:		
Pn	Pain	#(1-Yes,0-No)
Sg	Swelling	#(1-Yes,0-No)
Dge	Discharge	#(1-Yes,0-No)
if2 If yes	If yes,What	#(1-Serosanguineous,2- Pus,3-Others)
Signs:		
Wmth	Warmth	#(1-Yes,0-No)
Tness	Tenderness	#(1-Yes,0-No)
SR	Suture/Staple removed	#(1-Yes,0-No)
Wd	Wound Dehiscence	#(1-Present,0-Absent)
Investigations:		
Pus Cx	Pus culture	#(1-Yes,0-No)
if3 If yes	If yes,What	#(1-Significant growth,0-No growth)
RD	Radio Investigation	#(1-Done,0-Not done)
if4 If yes	If done,findings of deep incisional SSI/Abscess	#(1-Yes,0-No)
reop Re-op	Re-operation	#(1-Yes,0-No)
if5 If yes	If yes,evidence of deep incisional SSI/Abscess	#(1-Yes,0-No)
Dx	Dx by Surgeon	#(1-Infection present.2-Infection absent)
Wound assessment at 1st OP visit		
Symptoms:		

pn1 Pn Pain #(1-Yes,0-No)

sg1 Sg Swelling #(1-Yes,0-No)

dge1 Dge Discharge #(1-Yes,0-No)

if6 If yes If yes,What #(1-Serosanguineous,2- Pus,3-Others)

Signs:

wmth1 Wmth Warmth #(1-Yes,0-No)

tness1 Tness Tenderness #(1-Yes,0-No)

sr1 SR Suture/Staple removed #(1-Yes,0-No)

wd1 Wd Wound Dehiscence #(1-Present,0-Absent)

Investigations:

pus1 Pus Cx Pus culture #(1-Yes,0-No)

if7 If yes If yes,What #(1-Significant growth,0-No growth)

rd1 RD Radio Investigation #(1-Done,0-Not done)

if8 If yes If done,findings of deep incisional SSI/Abscess #(1-Yes,0-No)

reop1 Re-op Re-operation #(1-Yes,0-No)

if9 If yes If yes,evidence of deep incisional SSI/Abscess #(1-Yes,0-No)

dx1 Dx Dx by Surgeon #(1-Infection present.2-Infection absent)

Wound assessment at 1st month

Symptoms:

pn2 Pn Pain #(1-Yes,0-No)

sg2 Sg Swelling #(1-Yes,0-No)

dge2 Dge Discharge #(1-Yes,0-No)

if10 If yes If yes,What #(1-Serosanguineous,2- Pus,3-Others)

Signs:

wmth2 Wmth Warmth #(1-Yes,0-No)

tness2 Tness Tenderness #(1-Yes,0-No)

sr2 SR Suture/Staple removed #(1-Yes,0-No)

wd2 Wd Wound Dehiscence #(1-Present,0-Absent)

Investigations:

pus2 Pus Cx Pus culture #(1-Yes,0-No)

if11 If yes If yes,What #(1-Significant growth,0-No growth)

```
rd2 RD              Radio Investigation          #(1-Done,0-Not done)

if12 If yes          If done,findings of deep    #(1-Yes,0-No)
                  incisional SSI/Abscess

reop2 Re-op           Re-operation                #(1-Yes,0-No)

if13 If yes          If yes,evidence of deep     #(1-Yes,0-No)
                  incisional SSI/Abscess

dx2 Dx              Dx by Surgeon                #(1-Infection present.2-Infection
absent)
```

DATA SHEET

variable	sno	doe	name	age	sex	id	contact	addr
1	1	23/12/2012	Dipu Rani Das	57	2	276207	7.5E+09	East
2	2	23/12/2012	Fathima Edwin	68	2	677751	4.16E+10	119E
3	3	06/01/2013	PAYOOR PAUL JOHN	63	1	303908	9.89E+09	KN/3 NAG
4	4	09/01/2013	SAROJDAS	50	2	286035		E.E.
5	114	13/01/2013	ELUMALAI.M	24	1	287766	9.94E+09	KAN
6	5	20/01/2013	JOSEPH TSHERING LEPCHA	74	1	293908	9.43E+09	SICH
7	6	23/01/2013	ANISUZZAMAN.M.DR	48	1	377639	1.72E+08	167,
8	7	30/01/2013	UTTAM SHIT	22	1	300302	7.87E+09	EKAF
9	8	14/02/2013	MOSAMAD MOMTAZ AZHAR	14	2	397219	8.8E+09	C/35
10	9	17/02/2013	VENKATA SANDEEP	14	1	823003	9.85E+09	QUA
11	10	24/02/2013	MAKHAN SARKAR	51	1	290225	9.64E+09	BHEI
12	11	27/02/2013	SADDAM HUSSAIN	20	1	335922	9.83E+09	MAG
13	12	01/03/2013	SABITRI CHAKRAVORTY	44	2	423528	9.95E+09	BAK/
14	13	16/03/2013	Purabi Paria	33	2	251059	9.79E+09	NAM
15	14	01/04/2013	Jameela K M	62	2	368898		707A
16	15	03/04/2013	Pallabhi Hui	22	2	444551	9.61E+09	MOC
17	16	06/04/2013	RAMESH CHANDRA RAY MOHAPATRA	57	1	443909	9.44E+09	QTR
18	17	06/04/2013	Mamta Kumari	29	2	416650	9.93E+09	Chas
19	18	06/04/2013	Jarapala Ramesh Naik	17	1	444493	9.54E+09	A.B.
20	115	13/04/2013	Singrai Murmu	47	1	449643	9.55E+09	JAM
21	19	13/04/2013	AYISHA M.P.M.	35	2	352040	9.85E+09	FARO
22	20	16/04/2013	Chandra Maya Nepali	55	2	436088	9.79E+09	GAIS
23	21	20/04/2013	P.G.Mathai	63	1	363342	8.75E+09	Variy

24	22	27/04/2013	Bidhan Chandra Biswas	49	1	447918	9.9E+09	SARO
25	116	11/05/2013	Ponnurangam	61	1	466911	9.79E+09	1/26
26	117	19/05/2013	Goutam Gayen	36	1	428941	7.42E+09	DAB
27	118	19/05/2013	Nuni Bala Debi	46	2	368817	8.87E+09	MIRI
28	23	19/05/2013	Haidar Ali	50	1	418912	9.66E+09	ILAM
29	24	22/05/2013	Rajeshwara Rao	66	1	466297	9.4E+09	70-1
30	25	25/05/2013	Brojan Dronath	50	1	318204	1.75E+09	VARS
31	26	25/05/2013	Md Abdul Kaiom Sheikh	41	1	472702	9.85E+09	BOR
32	27	29/05/2013	Sk. Anwar Basha	41	1	453816	9.89E+09	3/55
33	28	01/06/2013	Reethamma	61	2	405742	1E+10	PRAI
34	29	09/06/2013	Baby Mishra	21	2	437967	9.61E+09	PALA
35	31	16/06/2013	Essakkithai	58	2	839842	9.89E+09	17,N
36	30	19/06/2013	Ram Dip Pandey	62	1	746205	9.33E+09	278,
37	32	01/07/2013	JAHURUL HOQUE MOLLA	71	1	488944	9.83E+09	AMG
38	33	10/07/2013	Sundaram	63	1	104899	9.95E+09	11/1
39	34	14/07/2013	JITENDRA NARAYAN SINGH	43	1	238345	8.76E+09	Q.NO
40	35	14/07/2013	Syed Murshid Ahmed	43	1	355793	7.6E+09	166
41	36	21/07/2013	Chaina Chakraborty	56	2	120024	7.5E+09	BACI
42	39	21/07/2013	Tahira Bibi	34	2	449348	8.94E+09	GOP
43	40	24/07/2013	Rajeshwari	66	2	467496	9.63E+09	41, L
44	42	03/08/2013	Pracheta Ranjan Chaulya	31	1	447689	9.65E+09	MON
45	43	03/08/2013	Bandana Das	50	2	463585	9.79E+09	TILK
46	41	08/08/2013	Santhosh Sen	45	1	491569	8.9E+09	BHU
47	45	11/08/2013	Sathiyamoorthy	44	1	418984	9.94E+09	2/31
48	46	18/08/2013	Debashis Guha	45	1	441372	8.1E+09	WES

49	47	18/08/2013	MD. Tofassal Hossain	62	1	468398	9.57E+09	DILA
50	48	25/08/2013	Khaleda Begum	40	2	633129	1.81E+09	FATH
51	49	25/08/2013	Harinder Mahto	38	1	640912	9.52E+09	KUN
52	50	25/08/2013	Laxmi Rani Das	37	2	637425	9.16E+09	DEW
53	51	29/08/2013	Kumar	59	1	430952	9.44E+09	31/1
54	52	28/09/2013	Bela Sarkar	33	2	477345	9.43E+09	PRA
55	54	05/09/2013	Dolan Chandra Hazari	48	1	649464	9.86E+09	NIZ
56	56	08/09/2013	JeyaKrushna Jena	49	1	484875	9.79E+09	MAY
57	57	08/09/2013	Sandhya Barman	58	2	658515	9.88E+09	148/
58	55	18/09/2013	Susamma George	56	2	670287	9.94E+09	KALA
59	58	21/09/2013	Theresemma	70	2	411640	9.45E+09	KAD
60	59	24/09/2013	Renji Daniel	44	1	665409	9.89E+09	FLAT
61	60	28/09/2013	Joydev Bhowmick	24	1	387301	8.14E+09	Amla
62	61	28/09/2013	Piyali Kundu	42	2	665399	9.66E+09	MAN
63	62	03/10/2013	Shyamal Ghosh	39	1	600709	9.8E+09	SRI F
64	63	03/10/2013	Aditya Bangal	48	1	683149	9.66E+09	BARI
65	64	06/10/2013	Molly	58	2	424325	9.9E+09	THA
66	65	07/10/2013	Jahangir Mondal	46	1	478651	8.22E+09	AMD
67	66	07/10/2013	Jharna Bagal	42	2	484083	8.65E+09	SALI
68	67	10/10/2013	Geetanjali Behera	58	2	682871	9.34E+09	NDIA
69	68	16/10/2013	Ram Naresh Singh	64	1	672740	9.39E+09	BART
70	69	20/10/2013	Ezra Prashanth	31	1	843482	9.89E+09	2/19
71	70	03/11/2013	Rupan Seal	33	1	678896	9.87E+09	UNS
72	72	20/11/2013	Indrapal Singh	38	1	663841	9.2E+09	SHIV
73	73	24/11/2013	Subba Lakshmi	65	2	188225	8.1E+09	28-5

74	74	12/12/2013	Chittaranjan Thakur	65	1	744035	9.66E+09	
75	75	15/12/2013	CHITYA RANJAN MALLICK	45	1	683745	9.18E+11	
76	76	15/12/2013	Jagdish Chandra Das	57	1	659010	9.62E+09	UDA
77	77	01/01/2014	Md. Abdus	61	1	746976	8.22E+09	01 ,0
78	79	12/01/2014	Nithyanandham	57	1	641563	9.09E+09	718,
79	80	12/01/2014	Bidyut Dutta	40	1	499768	9E+09	TULI
80	81	19/01/2014	Mani Achari	37	1	668224	8.94E+09	V. V.
81	82	26/01/2014	Jagdeeshwara Rao	38	1	787682	8.94E+09	15-3
82	83	30/01/2014	Rajamma Cheriyan	60	2	689858	8.3E+09	ALAH
83	85	02/02/2014	Malati Pakharin	43	2	781639	8.22E+09	201
84	86	02/02/2014	Ranganathan	65	1	358561	9.94E+09	BIG S
85	88	02/02/2014	Jai Deo Ram	47	1	784401	9.6E+09	BAIH
86	84	09/02/2014	Elsamma John	61	2	769275	9.84E+09	79/3
87	89	12/02/2014	Most Nargis Begum	58	2	686194	8.8E+11	UTTA
88	91	23/02/2014	Alpana Kundu	30	2	806189	8.88E+08	SRIN
89	93	02/03/2014	Rahil Topno	58	2	728434	9.94E+09	PARS
90	92	05/03/2014	Rammurat Jaiswal	47	1	761127	9.84E+09	BIRS
91	94	08/03/2014	Monoj Kr Sarkar	23	1	609212	8.49E+09	RAH
92	95	16/03/2014	MALOTI DAS	42	2	724368	8.51E+09	PUM
93	97	16/03/2014	Sumita Maji	36	2	814270	9.78E+09	BOLU
94	96	19/03/2014	MahaLakshmi	53	2	858844	9.17E+09	298
95	98	23/03/2014	Subramaniyan	61	1	807788	9.75E+09	3/57
96	99	30/03/2014	Sabita Byapari	41	2	808575	8.16E+09	KAM
97	100	30/03/2014	Arulmani	61	2	740329	9.44E+09	Villu
98	101	06/04/2014	Rafique Ahamad	43	1	799439	8.97E+09	KAE

99	102	12/04/2014	Gaffar Ali Mondal	56	1	786541	9.83E+09	RAJP
100	104	12/04/2014	Antony Dorai	81	1	621947	9.44E+09	C-35
101	106	20/04/2014	Sribas Maity	59	1	722315	9.8E+09	DHA
102	103	26/04/2014	Sarbani Makal	25	2	774839	9.6E+09	SANI
103	107	30/04/2014	Selvaraj	58	1	837967	9.63E+09	TOW
104	105	04/05/2014	Nadeem Ahamad	40	1	839393	9.61E+09	LANI
105	108	08/05/2014	Lutmon Lynshiang	54	2	839744	9.86E+09	LUM
106	109	07/05/2014	VijayaBaskar	37	1	780237	9.95E+09	DOO
107	111	10/05/2014	JoyShree Roy	23	2	780237	8.88E+09	WAF
108	112	10/05/2014	Deben Borah	60	1	272148	9.09E+08	POK/
109	119	18/05/2014	Sriivashini	30	2	840088	8.06E+09	36/1
110	120	18/05/2014	Tarun Roy	44	1	847743	9.84E+09	AGA
111	121	18/05/2014	Ganga	54	1	842405	9.75E+09	162,
112	123	25/05/2014	Kalaivani	59	2	751274	9.89E+09	167/
113	124	25/05/2014	Md. Jaffar Hossain	53	1	854893	1.83E+09	Chitt
114	125	01/06/2014	Pathipati Govinda Naidu	59	1	763137	9.97E+09	AND
115	126	01/06/2014	Rafael Golmes	68	1	765355	8.88E+08	Bang
116	110	10/05/2014	Alok Dey	51	1	775589	9.57E+09	WB
117	127	09/06/2014	Rajkumar Bijoy Singh	71		788887	9.44E+09	Man
118	128	16/06/2014	Pradip Dey	51	1	862616	9.36E+09	B'de
119	129	16/06/2014	John SunderRaj	67	1	819889	9.72E+09	Attu
121	131	16/06/2014	Shibani Sarkar	24	2	806825	9.43E+09	WB
122	132	18/06/2014	Bandana Mishra	46	2	902514	9.48E+09	WB
123	133	18/06/2014	Chiranjevi Jha	62	1	852395	8.29E+09	Jharl
124	135	18/06/2014	Sadhana Halder	59	2	822583	8.01E+09	WB

125	136	22/06/2014	Padmini	53	1	683167		
126	137	22/06/2014	Salma Bibi	31	2	858150	9.63E+09	WB
127	138	22/06/2014	Bishwanath Biswas	42	1	857935	9.83E+09	WB
128	139	29/06/2014	Sampa Kotal	26	2	910222	9.73E+09	WB
129	140	29/06/2014	Yesu Babu	47	1	874936	9.7E+09	AP
130	141	06/07/2014	Arun Saha	20	1	871563	7.42E+09	WB
131	143	06/07/2014	Sumithra Subba	37	2	891833	9.55E+09	WB
132	144	06/07/2014	Raju Baidya	23	1	891388	9.38E+09	WB
133	142	09/07/2014	IraBera	40	2	834853	8.94E+09	WB
134	145	09/07/2014	Baiju Varghese	50	1	879933	9.85E+09	Kera
135	146	20/07/2014	DhanaRangan Sharma	36	1	825162	7.67E+09	Bang
136	147	20/07/2014	Arjit Mridha	22	1	453685	7.67E+09	WB
137	148	24/07/2014	Radhesh Sharma	44	1	234213	9.6E+09	Biha
138	150	11/08/2014	Nirmal Khanra	47	1	825827	9.6E+09	WB

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